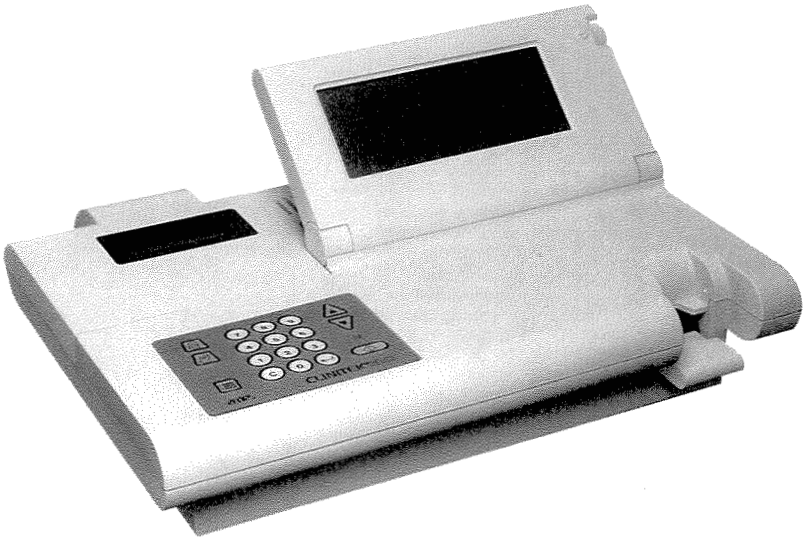
CLINITEK® 100

Urine Chemistry Analyzer



Operating Manual

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TABLE OF CONTENTS

Section		Page
1	**INTRODUCTION**	
	General Description	1.1
	Components and Mechanical Operation	1.1
	Keyboard	1.5
	Reagent Strip Feed Table	1.7
	Optical System	1.9
	Specifications	1.10
	Displayed/Printed Results (Tables 1-1 to 1-8)	1.11
2	**EXPLANATION OF SOFTWARE AND ROUTINES**	
	A. Main Menu	2.1
	B. Instrument Setup	2.5
	C. Analyze Mode	2.17
	D. STAT Mode	2.20
3	**INSTALLATION**	
	General	3.1
	Environmental Factors	3.1
	Unpacking	3.1
	Instrument Setup	3.3
	Interfacing to a Printer	3.4
	Interfacing to a Computer	3.5
	Initial Instrument Check	3.5
4	**OPERATING INSTRUCTIONS**	
	Activating the CLINITEK 100 Instrument	4.1
	Inspection of Reagent Strip Feed Table	4.2
	Instrument/Reagent Strip Performance Check	4.2
	Procedure for Urine Analysis	4.6
	Operating Notes	4.11
	When Testing is Complete	4.11
5	**ACCESSORIES**	5.1
6	**CARE OF THE INSTRUMENT**	
	General Cleaning	6.1
	Daily Cleaning	6.1
	Disinfection	6.4
	Periodic Maintenance	6.5
7	**TROUBLESHOOTING**	
	General Information	7.1
	Troubleshooting Chart	7.2
8	**MINOR REPAIR**	
	Replacement of Feed Table Insert	8.1
	Fuse Replacement	8.3
	Removal and Replacement of Printer Module	8.5
9	**SERVICE AND REPLACEMENT PARTS**	
	Where to Call for Service	9.1
	Preservice Checklist	9.2
	Replacement Accessory Items	9.3
	Replacement Parts	9.3
Appendix		
I	**COMPUTER AND PRINTER INTERFACE**	App I.1

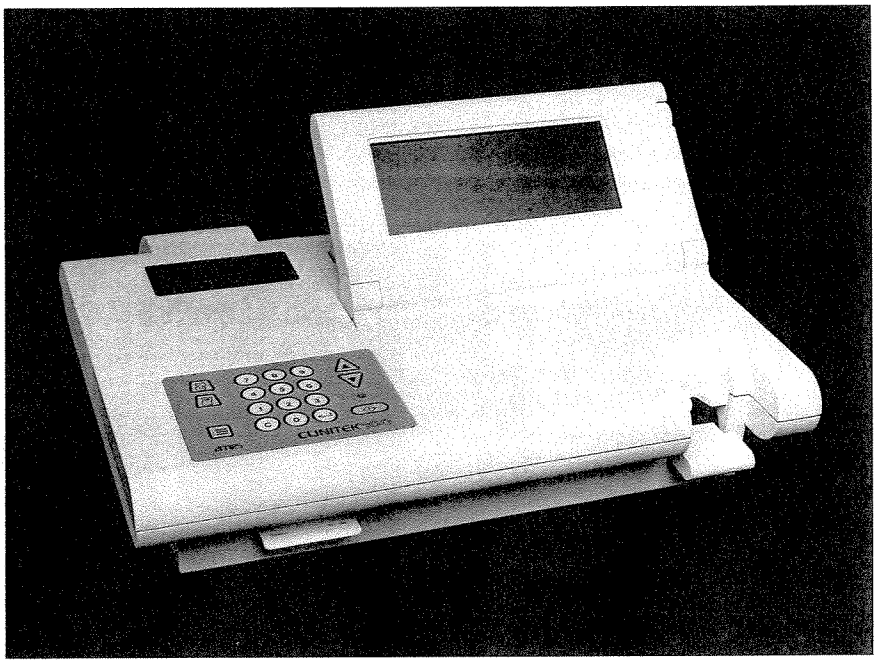


Figure 1-1
CLINITEK® 100 Urine Chemistry Analyzer

Figure 1-2
Front of the Instrument

INTRODUCTION

General Description

The CLINITEK® 100 Urine Chemistry Analyzer (Figure 1-1) is a semiautomated, benchtop instrument designed to "read" Bayer Diagnostics Reagent Strips for Urinalysis. The instrument system includes a Program Card that contains the programming necessary for the CLINITEK 100 instrument to read these Reagent Strips. The instrument is initially configured to read MULTISTIX® 10 SG Reagent Strips; in the United States, MULTISTIX® 9 and URISTIX® 4 Reagent Strips are also qualified for use. Outside of the United States, contact your Bayer Diagnostics representative or office for the products that can be used in your country.

Depending on the product being used, Bayer Diagnostics Reagent Strips contain reagent areas for testing glucose, bilirubin, ketone (acetoacetic acid), specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes. The CLINITEK 100 instrument is a reflectance photometer that analyzes the color and intensity of the light reflected from the reagent area and displays the results in clinically meaningful units (see Tables 1-1 through 1-8). No calculations are required.

Components and Mechanical Operation

Figures 1-2 through 1-4 show the major components of the CLINITEK 100 instrument. Reagent Strips are loaded onto the reagent strip feed table (1), which will automatically move out to the "load" position when the instrument is first turned *on*. Test results are printed by the internal thermal printer (2) (unless this option is deselected by the user). All communications between the operator and the instrument are made through the keyboard (3) and the display screen (4). The keyboard consists of 10 numeric keys (0 to 9), plus several special function keys. The display screen is an 8-line, 40-character liquid crystal display (LCD). Test results are displayed on the screen, in addition to multiple choice menus for selecting various modes and functions of the instrument. Selections from the menus and requested information are entered directly from the keyboard.

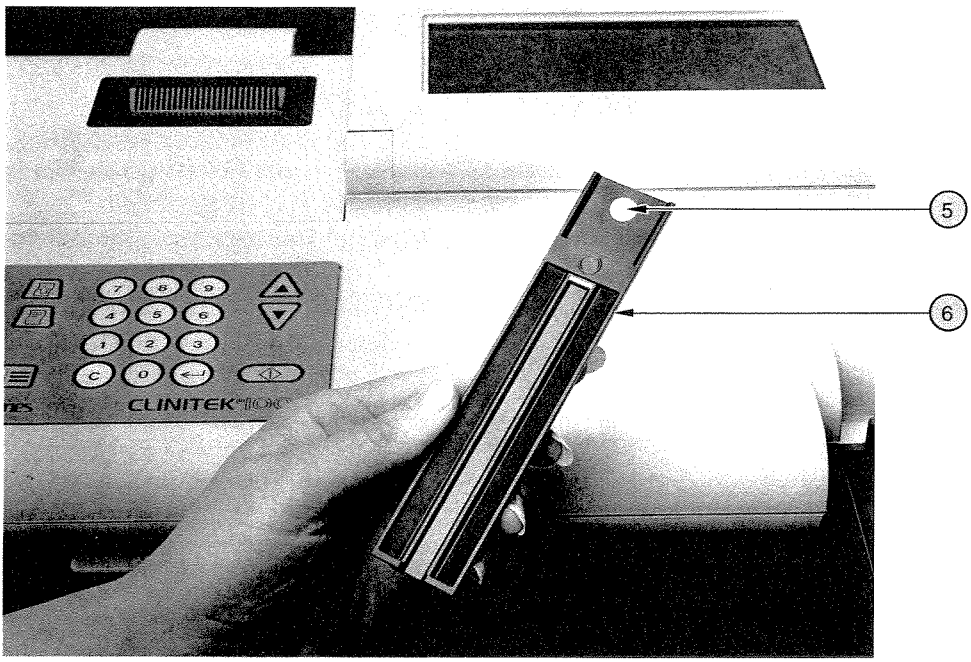


Figure 1-3
Reagent Strip Insert

Figure 1-4
Program Card and Receptacle

When the CLINITEK 100 instrument is first turned *on,* an optical calibration and self-test procedure is performed, during which the position of the feed table is checked and the light intensity of the optical system is checked and calibrated. Each time a Reagent Strip is read, another calibration procedure is performed, using a white plastic chip (5) that is located on the feed table insert (6). This calibration chip provides a reference reflectance surface for the internal calibration of the instrument's optical system. Calibration is accomplished automatically by the measurement of reflected light from the calibration chip surface. The calibration chip must be kept clean for proper instrument calibration.

All programming for the instrument is contained in a replaceable Program Card (7). The program card is programmed with such information as wavelengths, error messages, operating sequence, and the algorithms needed to convert reflectance into clinically meaningful results. The program card is inserted into the card receptacle (8).

Figure 1-5 shows the rear view of the CLINITEK 100 instrument. The line cord connects into the line cord receptacle (9), which is located on the power module (10). The power switch (11) is also located on the power module, as is the fuse holder (12), which protects against serious electrical overload. The interface connectors (13) are the points at which a computer and/or a form or 80-column printer may be interfaced with the instrument.

The instrument stores the operating parameters and up to 100 sets of patient results in a battery-backed RAM memory. This memory is saved in the instrument regardless of whether the power is *on* or *off.*

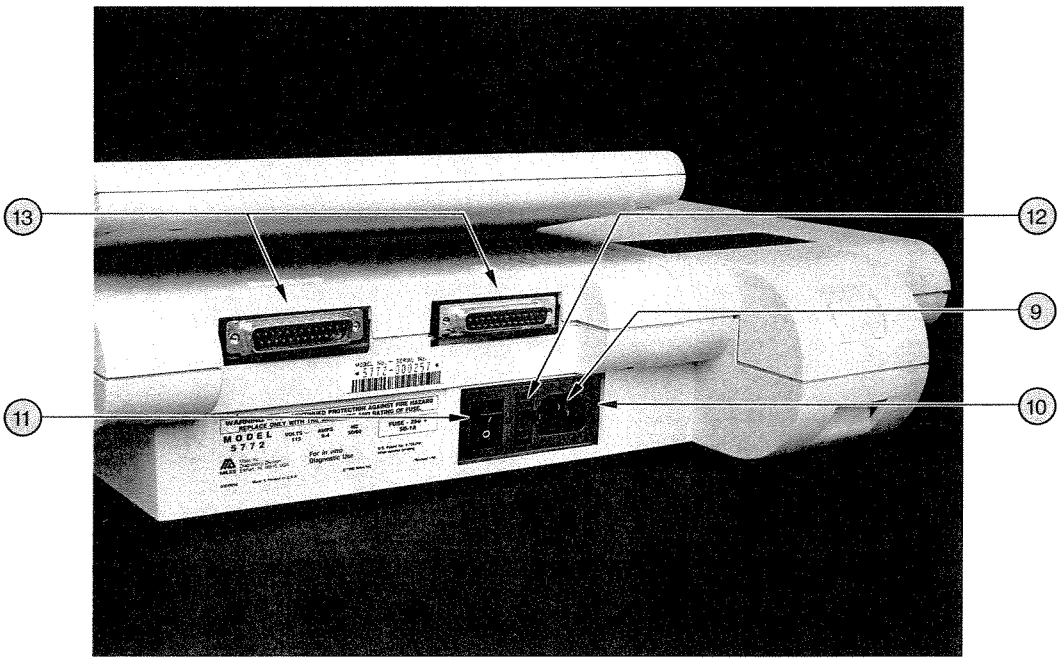


Figure 1-5
Rear of the Instrument

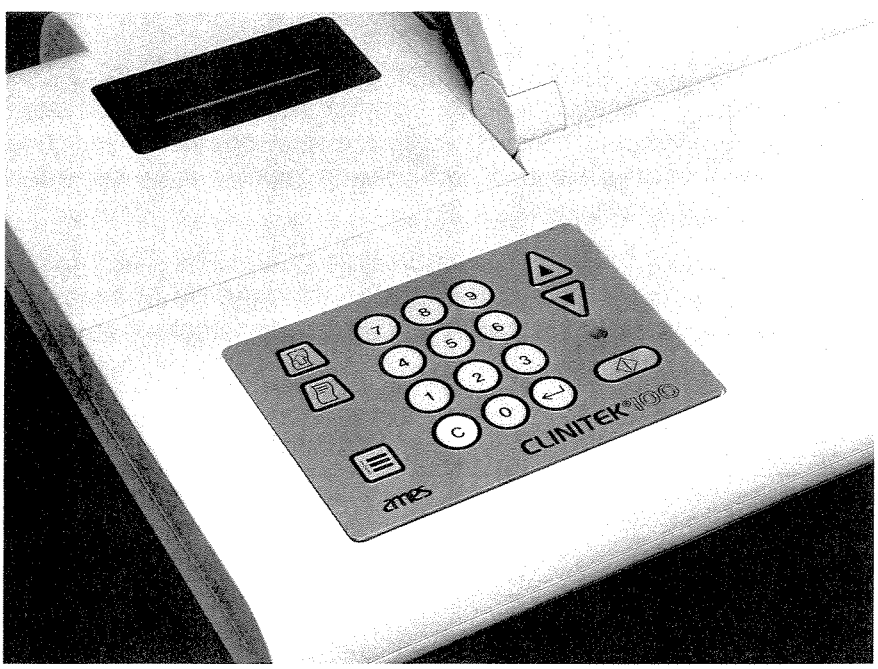


Figure 1-6
Keyboard

Keyboard

The keyboard (Figure 1-6) consists of a 10-digit numeric keypad (0 to 9) and 8 additional function keypads. A small green light is also located on the keyboard, directly above the ◇ key; this light illuminates when the power is turned *on.*

0 to 9	These keys are used to enter numerical information requested in the various displays.
◇ (START)	When this key is pressed, the instrument begins a timed analysis sequence that includes mechanical operation of the feed table. Pressing the ◇ key (START) when the instrument is in the **Analyze** Mode has no effect on instrument operation, as the key is inoperable during this mode. Movement of the feed table is delayed 10 seconds after pressing ◇. The delay allows for placement of the Reagent Strip onto the feed table and for reactions of the reagent test areas.
(MENU)	Pressing this key causes the display to return to the most previous menu screen (or in certain cases, directly back to the Main Menu). If a numeric entry is requested on a display, any changes made will be retained *only* if the ↵ key is pressed prior to pressing . The display can be returned to the Main Menu by pressing this key one or more times.

↵ (ENTER)	Pressing this key ends the input for the current field for which data is being entered or accepts the information that is currently highlighted or displayed.
C (CLEAR)	If an error is made in entering numerical information, this key can be pressed prior to pressing ↵ to erase any previously entered digits, allowing for them to be entered again. Once ↵ has been pressed, the C (CLEAR) key has no effect.
▲ (UP ARROW) ▼ (DOWN ARROW)	These two keys move the highlighting on a multiple choice menu to the next or previous line item. The movement of the arrow keys is circular; that is, if the first menu item is highlighted, pressing ▲ will cause the last item to be highlighted, and vice versa for the ▼ key. When the desired menu item is highlighted, pressing ↵ will cause that item to be selected.
(PRINT)	This key is used to print the results that are displayed when data files are recalled from memory (Data Recall Routine) or to reprint the displayed results while in the **Analyze** Mode (the instrument automatically prints each set of test results as soon as all results are available if either the internal or external printer has been selected).
(FEED PAPER)	Each time this key is pressed, the paper in the internal printer will be moved up 2 lines.

Reagent Strip Feed Table

The reagent strip feed table is a two-piece assembly designed to correctly hold and transport a Bayer Diagnostics Reagent Strip through the testing cycle. A Reagent Strip that has been dipped into a urine specimen and had excess urine removed must be correctly positioned in the strip holding channel, with the end of the strip positioned against the rear barrier of the feed table insert. **CAUTION: Avoid placing objects in the path of or onto the feed table at any time during instrument operation. Never push or pull the feed table during instrument operation.**

The feed table insert can be removed for cleaning and must always be correctly repositioned on the feed table. The insert is held in position by two rails and four plastic contact points, located under the insert (Figure 1-7). If a contact point becomes damaged, the feed table insert will not be properly held in place on the feed table and the Reagent Strips will not be properly positioned on the feed table insert. **Therefore, a defective feed table insert should always be replaced.**

The feed table insert contains the white plastic calibration chip that is used for instrument calibration. This calibration chip must be kept clean for proper instrument calibration (see Section 6, "Daily Cleaning"). The chip should be inspected periodically for scratches and scuffs; if damaged, the feed table insert should be replaced.

The feed table has two rest positions—out or "load" position, and in or "storage" position. The feed table will automatically move out to the "load" position when the instrument is turned *on.* To place the feed table in the "storage" position, gently push the table in to the end stop. **When the instrument is not in use, the feed table should be placed in the "storage" position.**

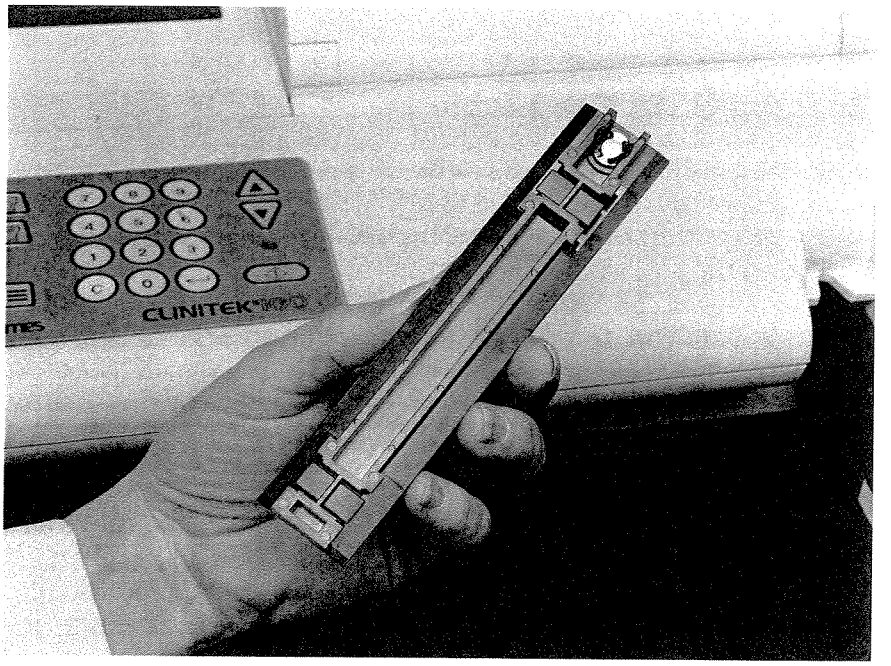


Figure 1-7
Underside of Reagent Strip Feed Table

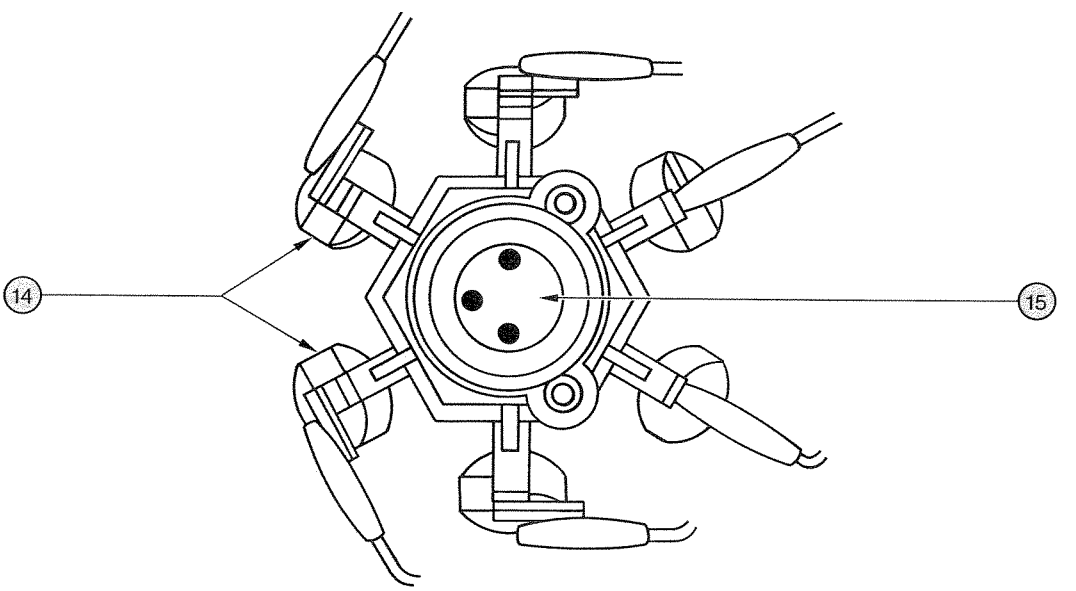


Figure 1-8
Optical System

Optical System

The optical system (Figure 1-8) consists of six LEDs (Light Emitting Diodes) and a photodiode. There are three pairs of LEDs (14), two each at 557 nm (green), 610 nm (amber), and 660 nm (red). The LEDs are situated in a circle around the photodiode (15), with each member of the matched pairs located directly across from one another.

The LEDs illuminate a fixed "read area" that is specially situated to reflect light back into the photodiode. The feed table moves the calibration chip and Reagent Strip test areas into the read area for instrument reading. The LEDs are automatically switched on and off for each strip reading cycle, and are electronically regulated to maintain a constant light output during each reading cycle. The illumination of the LEDs may be seen against the dark background of the feed table about an inch inside the instrument.

Light reflected from the surface of the reagent test area is detected by the photodiode where it is converted into electrical impulses. The impulses are processed by the instrument's microprocessor and converted into clinically meaningful results that are shown on the display screen and printed by the internal printer.

Specifications

Power Required:
115 VAC +10% / −15% 50/60 Hz
Optional—
100 VAC +10% / −15% 50/60 Hz
220 VAC +10% / −15% 50/60 Hz
240 VAC +10% / −15% 50/60 Hz

NOTE: The CLINITEK 100 instrument has been manufactured and inspected as a 115 VAC instrument. Before being used at any voltage other than 115 VAC, the instrument line cord, fuse, and/or rating label must be changed in order to comply with the specific requirements of each country.

***Line Leakage Current:**
<5 milliamperes

Dimensions:
Depth—32.0 cm (12.6 in.)
Width—39.4 cm (15.5 in.)
Height—11.2 cm (4.4 in.)
With display screen up:
21.6 cm (8.5 in.)

Weight: 3.86 kg (8.5 lbs.)

Ambient Operating Temperature Range:
18°C to 30°C (64°F to 86°F)

Ambient Operating Humidity Range:
20% to 85% Relative Humidity

Optimum Operating Conditions:
22°C to 26°C (72°F to 79°F) / 30% to 60% Relative Humidity
NOTE: Because of the nature of the urobilinogen and leukocytes reagent areas found on Bayer Diagnostics Reagent Strips, results for these two tests may be decreased at temperatures or humidity below the optimum conditions and vice versa.

The CLINITEK® 100 Urine Chemistry Analyzer (Models 5772 and 5772C) is listed by the Underwriters' Laboratories (UL) and the Canadian Standards Association (CSA) as certified. Model 5772C conforms to EMC Directive 89/336 Amendment 92/31/EEC and to the Low Voltage Safety Directive 73/23/EEC.

*Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL1262 and CSA 22.2 No. 151.

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negative 500 Trace >=1000 250	Negative 2+ Trace 3+ 1+
Bilirubin	BIL		Negative Moderate Small Large	Negative 2+ 1+ 3+
Ketone	KET	mg/dL	Negative 40 Trace >=80 15	Negative 2+ Trace 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negative 100 Trace >=300 30	Negative 2+ Trace 3+ 1+
Urobilinogen	URO	EU/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negative Positive	No Difference
Occult Blood	BLO		Negative Moderate Trace Large Small	Negative 2+ Trace 3+ 1+
Leukocytes	LEU		Negative Moderate Trace Large Small	Negative 2+ Trace 3+ 1+

Table 1-1
Displayed/Printed Results

ENGLISH CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/dL	– 0.5 0.1 >=1.0 0.25	– 2+ +/– 3+ 1+
Bilirubin	BIL		– 2+ 1+ 3+	No Difference
Ketone	KET		– 2+ +/– 3+ 1+	No Difference
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	– 100 +/– >=300 30	– 2+ +/– 3+ 1+
Urobilinogen	URO	EU/dL	0.1 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		– +	No Difference
Occult Blood	OB		– 2+ +/– 3+ 1+	No Difference
Leukocytes	WBC		– 2+ +/– 3+ 1+	No Difference

Table 1-2
Displayed/Printed Results

ENGLISH +/–
Units—Conventional, +/– System

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mmol/L	Negative 28 5.5 >=55 14	Negative 2+ Trace 3+ 1+
Bilirubin	BIL		Negative Moderate Small Large	Negative 2+ 1+ 3+
Ketone	KET	mmol/L	Negative 3.9 0.5 >=7.8 1.5	Negative 2+ Trace 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	Negative 1.0 Trace >=3.0 0.3	Negative 2+ Trace 3+ 1+
Urobilinogen	UBG	µmol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		Negative Positive	No Difference
Occult Blood	BLD	Ery/µL	Negative Ca80 Ca10 Ca200 Ca25	Negative 2+ Trace 3+ 1+
Leukocytes	LEU	Leu/µL	Negative Ca125 Ca15 Ca500 Ca70	Negative 2+ Trace 3+ 1+

Table 1-3
Displayed/Printed Results

ENGLISH S.I.
Units—International (S.I.)

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/L	NEGATIF 5.0 TRACES >=10 2.5	NEGATIF 2+ TRACES 3+ 1+
Bilirubin	BIL		NEGATIF MOYEN FAIBLE FORT	NEGATIF 2+ 1+ 3+
Ketone	CET	g/L	NEGATIF 0.4 TRACES >=0.8 0.15	NEGATIF 2+ TRACES 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	NEGATIF 1.0 TRACES >=3.0 0.3	NEGATIF 2+ TRACES 3+ 1+
Urobilinogen	URO	mg/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		NEGATIF POSITIF	No Difference
Occult Blood	SNG	GR/µL	NEGATIF env80 env10 env200 env25	NEGATIF 2+ TRACES 3+ 1+
Leukocytes	LEU	GB/µL	NEGATIF env125 env15 env500 env70	NEGATIF 2+ TRACES 3+ 1+

Table 1-4
Displayed/Printed Results

FRENCH CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mmol/L	NEGATIF 28 TRACE >=55 14	NEGATIF 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIF MOYEN FAIBLE FORT	NEGATIF 2+ 1+ 3+
Ketone	CET	mmol/L	NEGATIF 3.9 TRACE >=7.8 1.5	NEGATIF 2+ TRACE 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	NEGATIF 1.0 TRACE >=3.0 0.3	NEGATIF 2+ TRACE 3+ 1+
Urobilinogen	URO	µmol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		NEGATIF POSITIF	No Difference
Occult Blood	SNG		NEGATIF MOYEN TRACE FORT FAIBLE	NEGATIF 2+ TRACE 3+ 1+
Leukocytes	LEU		NEGATIF MOYEN TRACE FORT FAIBLE	NEGATIF 2+ TRACE 3+ 1+

Table 1-5
Displayed/Printed Results

FRENCH S.I.
Units—International (S.I.)

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negativ 500 Spur >=1000 250	Negativ 2+ Spur 3+ 1+
Bilirubin	BIL		Negativ Maessig Schwach Stark	Negativ 2+ 1+ 3+
Ketone	KET	mg/dL	Negativ 40 Spur >=80 15	Negativ 2+ Spur 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negativ 100 Spur >=300 30	Negativ 2+ Spur 3+ 1+
Urobilinogen	UBG	mg/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negativ Positiv	No Difference
Occult Blood	OBL	Ery/µL	0 Ca80 Ca10 Ca200 Ca25	Negativ 2+ Spur 3+ 1+
Leukocytes	LEU	Leu/µL	0 Ca125 Ca15 Ca500 Ca70	Negativ 2+ Spur 3+ 1+

Table 1-6
Displayed/Printed Results

GERMAN CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negativo 500 Indicio >=1000 250	Negativo 2+ Indicio 3+ 1+
Bilirubin	BIL		Negativo Moderado Bajo Alto	Negativo 2+ 1+ 3+
Ketone	CET	mg/dL	Negativo 40 Indicio >=80 15	Negativo 2+ Indicio 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negativo 100 Indicio >=300 30	Negativo 2+ Indicio 3+ 1+
Urobilinogen	URO	EU/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negativo Positivo	No Difference
Occult Blood	SAN	eri/µL	Negativo Ap 80 Ap 10 Ap 200 Ap 25	Negativo 2+ Indicio 3+ 1+
Leukocytes	LEU	cel/µL	Negativo Ap 125 Ap 15 Ap 500 Ap 70	Negativo 2+ Indicio 3+ 1+

Table 1-7
Displayed/Printed Results

SPANISH CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/dL	Negativo 0.5 Tracce >=1.0 0.25	Negativo 2+ Tracce 3+ 1+
Bilirubin	BIL		Negativo Medio Leggero Forte	Negativo 2+ 1+ 3+
Ketone	KET	mg/dL	Negativo 40 Tracce >=80 15	Negativo 2+ Tracce 3+ 1+
Specific Gravity	PS		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negativo 100 Tracce >=300 30	Negativo 2+ Tracce 3+ 1+
Urobilinogen	URO	EU/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negativo Positivo	No Difference
Occult Blood	SAN		Negativo Medio Tracce Forte Leggero	Negativo 2+ Tracce 3+ 1+
Leukocytes	LEU	Cel/µL	Negativo Ca125 Ca15 Ca500 Ca70	Negativo 2+ Tracce 3+ 1+

Table 1-8
Displayed/Printed Results

ITALIAN CONV.
Units—Conventional

EXPLANATION OF SOFTWARE AND ROUTINES

When the CLINITEK® 100 Urine Chemistry Analyzer is first turned *on,* the display will show the message "Instrument Calibrating–Please Wait." Once the calibration/self-test has been completed, the display will show the time and date, the name of the Bayer Diagnostics Reagent Strip that is programmed to be read, the software version, and the key prompts of MENU and START. For example:

```
Multistix 10 SG                    10-22-91
                                   03:08 pm

                  Clinitek 100
                  Version F3.00


MENU                                  START
```

Press the ☰ key (MENU) to display the Main Menu, from which all user-selectable options can be accessed.

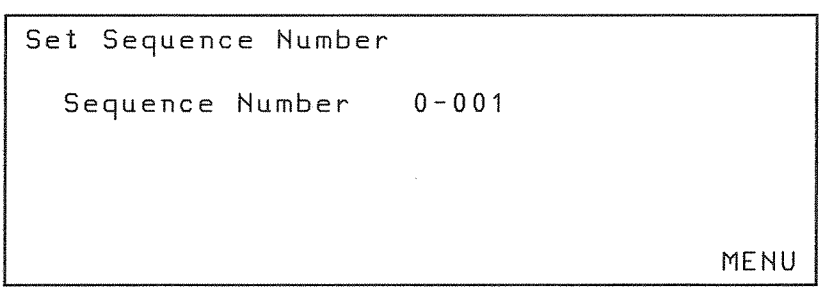
A. Main Menu

The Main Menu displays the time and date, the Reagent Strip name, and the sequence number assigned to the next specimen to be tested. It also lists a menu of options that can be selected by the user. For example:

```
Multistix 10 SG      0-001         10-22-91
                                   03:08 pm
Set Sequence No.
STAT Sample
Control Sample
Data Recall
Set Up Instrument
Print Load List                       START
```

One option in the list will be highlighted; that is, the type will be reversed out of a dark block. The ▼ and ▲ keys move the highlighting up and down the list. When the desired option is being highlighted, press ↵ to select that option.

1. **Set Sequence No.**
   The sequence number that will be assigned to the next test is displayed in the center of the top line of the display. The number consists of two parts, a prefix number and a sequential sample identification number. A different prefix number, from 0 to 9, can be assigned to distinguish between different instruments, work shifts, or operators. This number will precede the sequential ID number printed with each set of results. The sequential ID number increments with each test and may be set to any number from 001 to 999.
   a. If the sequence number being displayed is correct and does not need to be changed, do nothing; move the highlighting to the next desired option or begin testing samples, as instructed in Part C below, "ANALYZE MODE."
   b. If the sequence number needs to be changed from that being displayed, use the ▲ or ▼ keys as necessary to highlight the option "Set Sequence No.", then press ↵ to select the option. The next display will show, for example:



   The blinking cursor will be located on the first digit of the existing number. Press the appropriate numeric keys on the keypad to enter the desired number. The blinking cursor will move one position to the right with each entry. Both the prefix number and all three digits of the sequential ID number must be entered, including any leading zeros.

When the correct number has been entered, press [↵] ; if an error is made, press [C] (CLEAR) and enter the correct number, pressing [↵] when it has been entered. The display will return to the Main Menu, with the newly entered sequence number displayed.

NOTE: If only the prefix number needs to be changed, with the rest of the sequence number remaining as it is currently displayed, the new prefix can be entered, immediately followed by [↵] ; the sequential ID number will not be changed. (Pressing either [↵] or [123] prior to making *any* changes will return the display to the previous menu *without* changing the existing number.)

2. **STAT Sample**
   The prefix number of the sequence number can be changed to a prefix of "S" to denote a STAT sample by highlighting the "STAT Sample" option on the menu, then pressing [↵] . The sequence number shown on the top line of the display will then show "S-xxx," with the sequential ID portion of the number remaining unchanged. If a load list is in memory, use of the STAT sample option interrupts the display of loadlisted ID numbers and allows the ID number of the STAT sample to be entered. After a single test has been run, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted. The "S" prefix can be removed without running a test by merely pressing [↵] a second time. The sequence number that is printed on the report will also reflect the "S" prefix.

3. **Control Sample**
   In the same manner as for "STAT Sample" above, the prefix can be changed to a "C" to denote a control specimen by highlighting the "Control Sample" option on the menu and pressing [↵] . The sequence number shown on the display will show "C-xxx," with the sequential ID portion of the number remaining unchanged. As with a STAT sample, use of the control sample option interrupts the display of loadlisted ID numbers if a load list is in memory. After a

single test has been run, the prefix will return to the assigned number and the use of loadlisted ID numbers (if being used) returns to the point at which the run was interrupted. The "C" prefix can be removed without running a test by merely pressing ↵ a second time. The sequence number that is printed on the report will also reflect the "C" prefix.

4. **Data Recall**
   Up to 100 sets of test results are stored in the memory of the CLINITEK 100 instrument. Each of these data files can be recalled by highlighting "Data Recall" on the Main Menu and pressing ↵ . The most recently-run test will be displayed first. Pressing the ▼ key will recall the next earlier file and vice versa. The arrow keys are circular: if the most recent file is being displayed, pressing ▲ will recall the earliest file in memory (up to 100 samples); if the earliest file is being displayed, pressing ▼ will recall the most recent file. The displayed file can be reprinted by any active printer (external and/or internal) by pressing (PRINT). When all desired files have been recalled, press ☰ to return to the Main Menu or ◇ to test a new sample.
   NOTE: After a data file is transmitted to a computer, it is no longer retained in memory and is not available for recall through the "Data Recall" option.

5. **Set Up Instrument**
   When "Set Up Instrument" is highlighted and ↵ is pressed, the Setup Menu will be displayed. This menu lists numerous options by which changes can be made to the time and date, data output can be designated, and several data management capabilities selected. Each of these options are explained in Part B, Instrument Setup.

6. **Print Load List**
   If a load list is present in the memory of the instrument, it can be printed by highlighting "Print Load List" and pressing ↵ .
   NOTE: A load list can be downloaded from a host computer anytime the CLINITEK 100 screen is displaying the "START" prompt (e.g., from the Main Menu, after testing

of a Reagent Strip has been completed and printed, or from a "Data Recall" screen). As soon as the transmission is complete, the load list will be printed by the CLINITEK 100 printer. The load list can then be reprinted at any time through the "Print Load List" prompt.

B. Instrument Setup

When "Set Up Instrument" is selected from the Main Menu, the Setup Menu will be displayed as:

```
Setup Menu

  Set Time and Date     Use ID Numbers
  Clear Memory          Use Color/Clarity
  Printer               Select Tone
  Computer Port         Use Plus System
  Time & Date Format    Status
  Identify Abnormals                  MENU
```

1. **Set Time and Date**
   When "Set Time and Date" is highlighted and ↵ is pressed, a new menu will display two options: "Set Time" (which will be highlighted) and "Set Date."
   a. To change the **time,** press ↵ . The display will show the current time, along with an indication of the format in which the time is being displayed; the cursor will be located on the first digit of the time. For example:

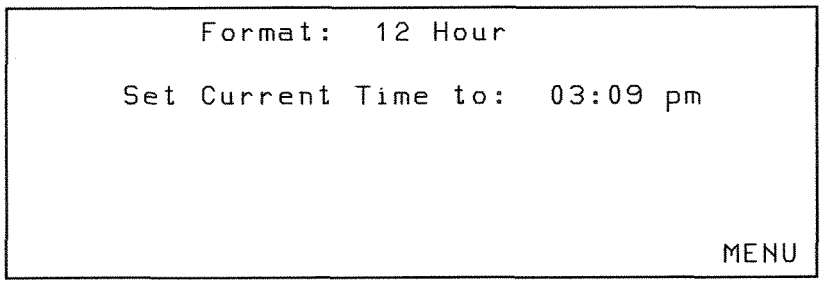
```
          Format:  24 Hour

      Set Current Time to:  15:09




                                    MENU
```

or for example:

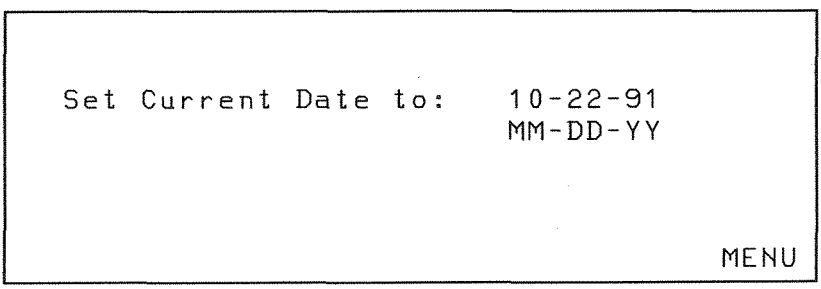


i. Enter the correct time in the format shown by pressing the appropriate numeric keys, then press ↵ . Be sure to enter leading zeros for any numbers lower than 10.
NOTE: If ↵ is pressed before all digits have been entered, only those digits to the left of the cursor will be changed; all others will remain unchanged. Therefore, if only the hour needs to be changed, the correct digits for the hour can be entered, followed by ↵ ; the minutes already being displayed will remain unchanged.

ii. If the clock is in the 12 Hour Mode, the display will show the options for "am" and "pm," with the current designation highlighted. Use the ▲ or ▼ key to move the cursor to the appropriate designation, if necessary, and press ↵ .

iii. The display will return to the Setup Menu.

b. To change the **date,** move the cursor until "Set Date" is highlighted, then press ↵ . The display will show the current date, along with the format in which the date is being displayed; the cursor will be located on the first digit of the date. For example:



i. Enter the correct date **in the format shown** by pressing the appropriate numeric keys, then press ↵ . Be sure to enter leading zeros for any numbers lower than 10. The display will return to the Setup Menu.

NOTE: If ↵ is pressed before all digits have been entered, only those digits to the left of the cursor will be changed; all others will remain unchanged.

NOTE: If the **format** of the time or date is incorrect (that is, 12 Hour vs. 24 Hour time; month/day/year vs. day/month/year vs. year/month/day for the date), it can be changed through the "Time & Date Format" prompt (see Step B-5 below).

2. **Clear Memory**

   If you wish to clear the instrument's memory, move the cursor until "Clear Memory" is highlighted, then press ↵ . The following screen will display the number of records in memory and confirm whether you wish to clear the memory; for example:

```
059 Records In Memory
Clear Memory?

  No
  Yes


                                MENU
```

   If you are certain you wish to clear the memory, move the cursor to highlight "Yes" ("No" will always be highlighted initially to help prevent accidental clearing of the memory) and press ↵. The display will return to the Setup Menu.

3. **Printer**

   Results can be printed by the internal printer and/or one of two styles of external printers. The CLINITEK® Form Printer can be used, by which results are printed on 3-copy

forms (see Section 5, ACCESSORIES); in addition, most 80-column, continuous feed, parallel printers are acceptable. Use of the internal instrument printer and/or an external printer can be selected through this prompt. Highlight this prompt to select the desired printing configuration and press ↵. The Printer Menu will be displayed as:

```
Select Printer

   Internal Printer
   External Printer
   Both
   None

                                        MENU
```

a. Use of the internal printer is selected by default; this printer can be turned *off* by selecting either "None" or "External Printer." Select the desired printer configuration by using the ▲ and ▼ keys to highlight the desired selection, then press ↵.
b. If "External Printer" or "Both" was selected, the next screen will request selection of the type of external printer:

```
Select External Printer Type

   80-Column
   Form Printer



                                        MENU
```

   Highlight the desired printer and press ↵.
c. The display will return to the Setup Menu.

4. **Computer Port**
If you wish to interface the CLINITEK 100 to a computer, press ↵ after highlighting the prompt "Computer Port." The following screen will be displayed:

```
Computer Port

  ON
  OFF
  Baud Rate


                                MENU
```

a. If a computer interface is not desired, highlight the menu option "OFF" and press ↵ ; the display will return to the Setup Menu.
b. If the CLINITEK 100 instrument will be interfaced to a computer, the appropriate Baud rate must be selected; in doing so, the computer port will be automatically turned *on.* Highlight the menu option for "Baud Rate" and press ↵ . The next screen will display the various Baud rates from which to select:

```
Select Baud Rate

  300
  600
  1200
  2400
  4800
  9600                          MENU
```

Use the ▲ and ▼ keys to highlight the Baud rate that is appropriate for the computer to which the CLINITEK 100 will be interfaced, then press ↵ . *(Failure to select the appropriate Baud rate may result in lost data.)* The display will return to the Setup Menu. When the ▲ and ▼ keys are used to highlight the desired Baud

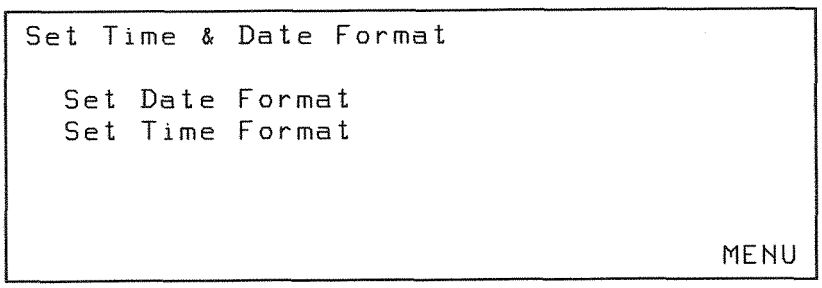
rate, followed by pressing ↵, the computer port is automatically turned *on*. If the default Baud rate of 4800 is the desired option, the ▲ and ▼ keys must still be used to highlight this option before pressing ↵ in order to automatically turn the computer port *on*.

NOTE: The computer port can be turned *off* or *on* without changing the Baud rate by highlighting the desired status in the Computer Port Menu and pressing ↵.

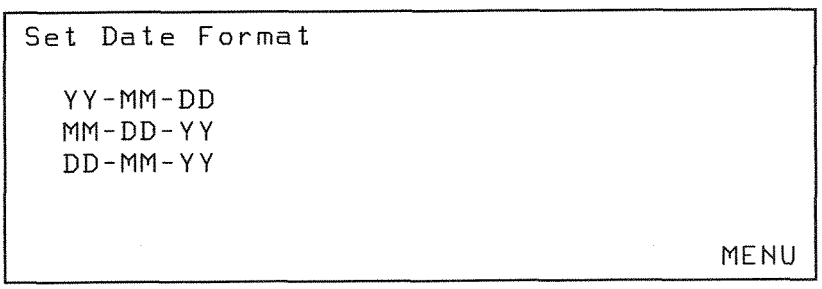
CAUTION: Turning the computer port *on* or *off*, or changing the Baud rate, automatically clears the memory. Therefore, be sure all patient results that have been previously run have been printed before making any changes to these screens.

NOTE: If the computer port is *on* and results have not been transmitted to a computer, the instrument will display a message of "MEMORY FULL" when the memory contains 100 sets of results. Some or all of the results must then be transferred to the computer or the memory must be cleared before additional samples can be tested. If the computer port is *off* and the memory contains 100 sets of results, testing can continue; however, each new set of test results will overwrite the earliest set of results (that is, the results for specimen #101 will replace the file for specimen #1, #102 will overwrite #2, and so on). When a file has been overwritten, it is no longer stored nor available for recall.

5. **Time & Date Format**
   Several formats for displaying the time and date are available and can be selected by the user through this prompt. The time can be displayed as 12 hour (am/pm) or as 24 hour (military) time; the date can be displayed as month-day-year (MM-DD-YY), day-month-year (DD-MM-YY), or year-month-day (YY-MM-DD). Upon selecting this prompt from the Setup Menu, the following will be displayed:

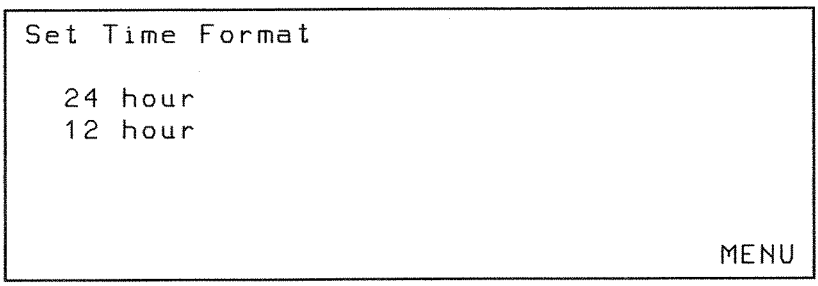


a. To change the date format, highlight "Set Date Format" and press ↵. The next screen will allow you to select the desired date format:



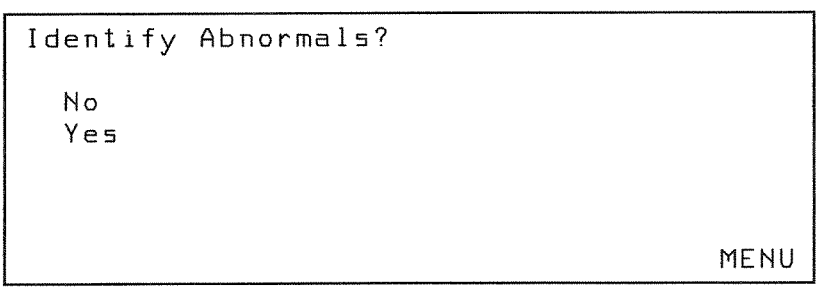
The format currently selected will be highlighted. Use the ▼ and ▲ keys to move the highlighting to the desired format, then press ↵. The display will then return to the Setup Menu; the date that is displayed in the Main Menu will immediately reflect the new format. **NOTE:** If the date format is changed, any records that were stored in memory prior to the change will reflect the new format if they are subsequently printed. That is, regardless of what date format was used when a record was stored, the current format will be reflected if a record is printed through the "Data Recall" prompt in the Main Menu.

b. To change the **time** format, highlight "Set Time Format" and press ↵. The next screen will allow you to select the desired time format:

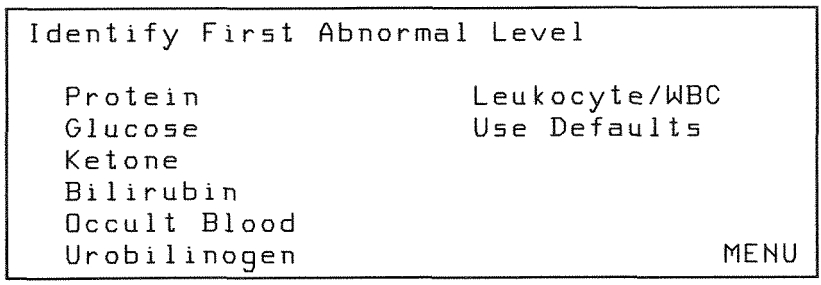


The format currently selected will be highlighted. Use the ▼ and ▲ keys to move the highlighting to the desired format, then press ↵ . The display will then return to the Setup Menu; the time that is displayed in the Main Menu will immediately reflect the new format.

6. **Identify Abnormals**
   Results greater than negative can be flagged on the display of results and on the printed report, if desired. Abnormal results are highlighted on the display and an asterisk is printed beside the test name on the printed report. The status of this option can be changed by selecting the prompt "Identify Abnormals" from the Setup Menu:



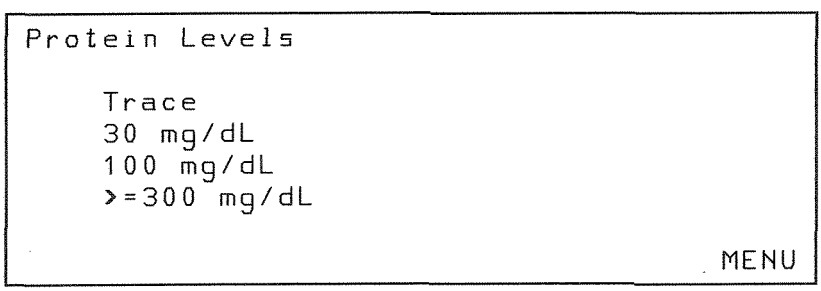
   a. The current status will be highlighted. Move the cursor to highlight the other option, if needed, then press ↵ . If "No" is selected, the display will return immediately to the Setup Menu. If "Yes" is selected, the screens will continue as shown below:



b. The first level at which results will be flagged can be selected separately for each of the reagent tests listed, or default levels can be used. The following list shows the values that will be flagged as abnormal if the default levels are used:

Protein Glucose Ketone Bilirubin Occult Blood Nitrite Leukocyte	All values greater than Negative
Urobilinogen	≥2.0 EU(mg)/dL (≥33 μmol/L)

If the default values are not desired for one or more tests, each test for which a change is desired can be selected from the menu being displayed. Upon selecting a specific test, all possible results greater than negative will be displayed; for example, if protein is selected:



The currently selected level will be highlighted. Move the cursor to highlight the level at which you desire flagging to occur (the selected level will also be flagged) and press ↵. The display will return to the previous menu (Identify First Abnormal Level) for additional changes. Refer to Tables 1-1 to 1-8 for the designations of positive results for your particular Reagent Strip and language.

NOTE: If you wish to use the default values for all tests except one (for example, Protein), select "Use Defaults" first, then select the test for which a change is to be made (in this example, Protein), and select the desired level at which flagging will occur.

c. When all selections have been made, press MENU to return to the Setup Menu.

7. **Use ID Numbers**

If desired, an identification (ID) number can be entered for each specimen. This number is in addition to the sequential number assigned to each specimen by the instrument. The ID number (up to 10 digits) can be an accession number or patient identification number (such as social security number). If you desire to download ID numbers from a host computer to create a load list, this option *must* be used ("Yes" must be pressed). Highlight the prompt "Use ID Numbers" and press ↵ to select this option:

```
Use ID Numbers?

  No
  Yes

                                    MENU
```

The current status of the option will be highlighted. Move the cursor to highlight the desired response, then press ↵. The display will return to the Setup Menu.

NOTE: Turning the ID option *off,* then back *on,* will clear the load list that is currently in memory.

8. **Use Color/Clarity**
The color and clarity of each specimen can be entered into each record by choosing from a rotating set of options that are displayed as each patient sample is being tested. There are eight descriptions for color (Yellow, Dk Yellow, Straw, Amber, Green, Orange, Red, and Other) and five descriptions for clarity (Clear, Sl Cloudy, Cloudy, Turbid, and Other). Highlight the "Use Color/Clarity" prompt and press ↵ to select this option:

```
Use Color/Clarity?

  No
  Yes


                                    MENU
```

The current status of the option will be highlighted. Move the cursor to highlight the desired response, then press ↵ . The display will return to the Setup Menu.

9. **Select Tone**
A tone will sound on the CLINITEK 100 after the instrument calibration and Self Test have been completed and after all tests on each Reagent Strip have been read and displayed during the **Analyze** Mode. The *pitch* (as opposed to volume) of this tone can be selected, or the tone turned *off* completely, through this prompt.

```
Select Tone Level

  LOW
  MED
  HIGH
  OFF

                                    MENU
```

The current status will be highlighted. Use the ▼ and ▲ keys to highlight the desired pitch of the tone, or to "OFF" to eliminate the tone completely, then press ↵. The display will then return to the Setup Menu.

NOTE: A different tone will sound whenever there is an error condition. This error tone *cannot* be changed or turned *off.*

10. **Use Plus System**

Results for several of the tests can be displayed in the Plus System, rather than as semi-quantitative descriptions or units, through this prompt. Tables 1-1 through 1-8 in Section 1 show the relationship between the semi-quantitative units and the Plus System. Upon selection of this prompt, the following screen is displayed:

```
Use Plus System?

  No
  Yes


                                MENU
```

The current status will be highlighted. Move the cursor to the desired response and press ↵. The display will then return to the Setup Menu.

NOTE: A change in status (either selecting or deselecting the Plus System) will change the format in which all results in memory are displayed and printed accordingly; the designations for identifying abnormals will also change accordingly.

11. **Status**
    Upon selecting this prompt, the display will show the status of all previously-made selections, plus show the name of the Bayer Diagnostics Reagent Strip being used, the number of records in memory, and the Seq # that will be assigned to the next test. For example:

```
Instrument Status

Multistix 10 SG          Color/Clarity    ON
Internal Printer  ON     Sequence No. 1-115
External Printer  ON     Memory Used      052
   Form Printer          Plus System      OFF
Computer 9600     ON     Abnormals         ON
ID Numbers        ON
```

    Press [1 2 3] to return to the Setup Menu and again to return to the Main Menu.

C. ANALYZE MODE

The **Analyze** Mode is the normal operating mode of the CLINITEK 100, in which all urine testing is performed. The mode is initiated upon pressing the [◇] key. This is done immediately after the Bayer Diagnostics Reagent Strip has been dipped into and removed from the patient urine or control specimen. *To run a STAT specimen, especially if a load list is present, the "STAT Sample" option must be selected from the Main Menu* ***before*** *pressing* [◇]. The following events occur after pressing [◇]:

1. The display changes to the Test Screen, which shows the sequence number (Seq. No.) of the strip being tested and the message "Place Strip on Table." Fields for entering the ID number, color, and clarity will also be shown if these options were selected through the Instrument Setup Routine.
2. Approximately 10 seconds after [◇] was pressed, the reagent strip feed table will move into the instrument for reading of the reagent tests. As each test is read, the result is displayed on the screen. Abnormal results will be highlighted on the screen, if this option was selected through the Instrument Setup Routine. The display for the occult blood test will be blank until the result is available. If the strip contains a reagent area for leukocytes, the display will show a series of

dashes (---) in place of the result for "LEU" until the leukocytes result is obtained. It will be displayed as soon as it is available. (The SG result may also briefly show a series of dashes while waiting for the pH test result; this allows the instrument to automatically adjust the SG result according to the pH reading [refer to the package insert for your Bayer Diagnostics Reagent Strips for further information on this adjustment].)

3. If the options for using specimen ID and/or color/clarity have been selected, the information can be entered or confirmed at the user's convenience during and after the testing cycle. The easiest times to enter data are:
   - immediately after the strip is placed onto the feed table,
   - while waiting for the leukocyte result, and
   - after all results have been displayed.

   Data can also be entered at almost any time during the testing cycle; however, the keyboard will lock when the instrument is actually taking a reading, so any key that is pressed during this time will not respond immediately. (Several keystrokes can be held in memory and will be displayed after the reading has been taken.) Enter the requested information as instructed in Steps 4-6 below.

4. a. **If ID numbers have been loadlisted,** the first number in the list will be displayed in the ID number field. If the number being displayed agrees exactly with the specimen being tested, press [↵] . If it does not agree, either:
      i. Enter the correct ID number using the numeric keyboard, directly replacing the number being displayed, or
      ii. Press [C] (CLEAR) to erase the number. If the [C] key is used, the ID number that was initially displayed will be lost and will be replaced by the next number in the load list. Repeat Step 4-a to enter the correct ID number.

   NOTE: As long as a load list is present in the instrument's memory, the abbreviation "LDLST" (for "Loadlist") will appear on the display screen. When the final ID number has been removed from the load list, "LDLST" will no longer be displayed.

b. **If there are no numbers in a load list,** either because they have all been tested or because a load list was not present initially, enter the ID number using the numeric keyboard. Up to 10 digits can be entered. When the number has been correctly entered, press ↵. If an error is made, press C (CLEAR) and enter the number again.

5. The cursor will move to the Color field, where the default color of "Yellow" will be displayed. To change the displayed description, press the ▼ or ▲ keys until the desired description is being displayed, then press ↵.

6. The cursor will move to the Clarity field, where the default value of "Clear" will be displayed. Change the displayed description, if necessary, by pressing ▼ or ▲ until the desired description is being displayed, then press ↵.

7. As soon as all results have been displayed and the ID number, color, and clarity have been entered (if these fields were displayed), the results will be printed by the internal printer and/or external printer (depending upon which printer option was selected through the Instrument Setup Routine). While results are being printed, the keyboard is locked. Once printing is complete, however, the display of results will also list the active keys of "MENU" and "START." **NOTE:** If using a Form Printer, insert the form into the printer while the Reagent Strip is being read. The results will then be printed onto the form when they are available. If a form is not present in the printer when the results are transmitted, a "Printer Error" message will be displayed; after returning to the Main Menu, ensure that a form is in place and press the key to resend the last set of results.

8. Remove and discard the used Reagent Strip.

9. a. To run another test, dip a fresh strip into the next specimen, and press ◇ as soon as the strip is removed from the specimen; or
   b. press ☰ to return to the Main Menu.

D. STAT MODE

If it is necessary to run a STAT specimen during a run, the normal routine using loadlisted specimens can be interrupted and the sequence number can be altered to reflect an "S" prefix.

1. To enter the STAT Mode, return the display to the Main Menu (by pressing the MENU key) *before* beginning the testing sequence for the STAT specimen.
2. Use the ▲ and ▼ keys to highlight the "STAT Sample" option and press ↵. The sequence number will be changed to reflect a prefix of "S."
3. The STAT specimen can now be analyzed in the normal manner. After pressing ◇ and placing the Reagent Strip on the feed table, the ID number and/or color/clarity can be entered, if these options have been selected. If a load list is present in the instrument's memory, display of the loadlisted ID numbers will be interrupted for the STAT specimen, allowing the STAT ID number to be entered.
4. After the STAT specimen has been analyzed and the result printed, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted.

INSTALLATION

General

This section provides detailed installation instructions for the CLINITEK® 100 Urine Chemistry Analyzer. The installation steps must be followed correctly to ensure proper installation, operation, and service. Read this Operating Manual carefully before attempting to operate the CLINITEK 100 instrument. Follow all instructions carefully.

The CLINITEK 100 is a precision instrument and must be handled accordingly. Rough handling or dropping of the instrument will disturb internal calibrated optics and electronics and/or cause other damage. Always handle the instrument with care.

Environmental Factors

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature should be held relatively constant to obtain the highest degree of operating stability. The ambient temperature range for instrument operation is 18°C to 30°C (64°F to 86°F); the ambient operating humidity range is 20% to 85% relative humidity. The *optimum* operating conditions are 22°C to 26°C (72°F to 79°F) and 30% to 60% relative humidity. Before operating, allow the instrument to equilibrate to the environmental conditions.

Place the instrument where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, ovens, hot plates, open burners, radiators, dry ice baths, and in particular, to direct sunlight. The CLINITEK 100 should not be used in an explosive atmosphere.

Unpacking

1. Carefully remove the CLINITEK 100 instrument and accessory package from the shipping carton. Inspect the carton and instrument for visible signs of damage. If damage to the instrument exists, immediately file a complaint with the carrier.

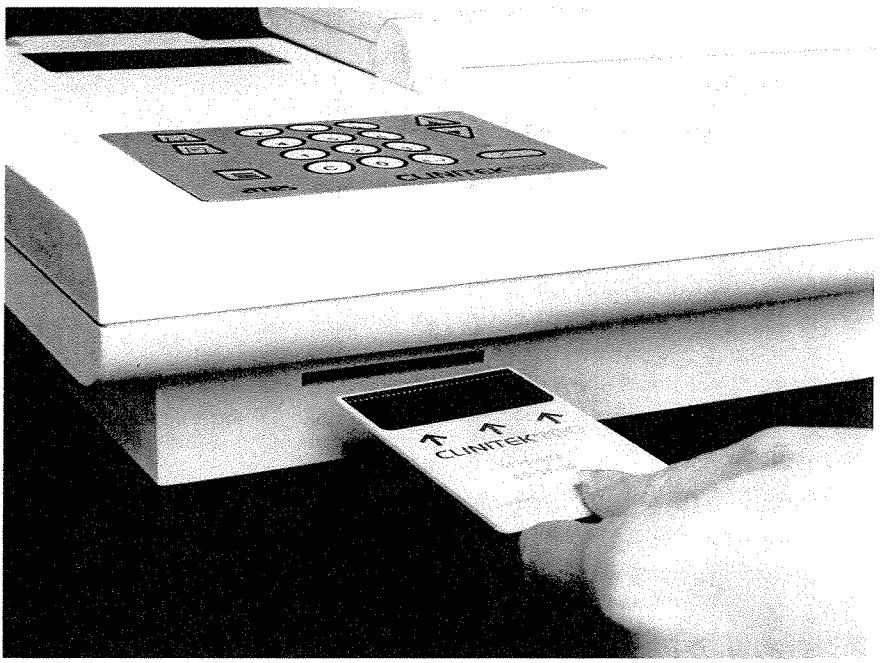


Figure 3-1
Inserting the Program Card

2. The following parts and accessories should be included with the instrument:
   - Operating Manual (1)
   - Program Card (1)
   - Line Cord (1)
   - Feed Table Insert – 4¼" (1)
   - Paper Rolls (2)
   - Warranty Card (1)
   - Replacement Fuse (1)

   Depending on the specific country, the following items may be included:
   - System Information Card (1)
   - Multi-language sheet of labels (1 each):
     - feed table insert labels
     - rating labels

   Make sure all these items have been included with your instrument, and keep them for future use.

3. After the instrument has been unpacked, place it on a firm work surface in the designated work area. Make sure there is nothing in front of the instrument that will obstruct the reagent strip feed table when it moves out to the "load" position.
   NOTE: Retain the CLINITEK 100 shipping carton for future use. If the instrument ever needs to be shipped, the shipping carton will afford the best protection.

Instrument Setup

1. Plug the Program Card into the instrument by inserting it into the card receptacle and pressing it in firmly until it "snaps" into place (Figure 3-1). The side containing the metal ridges is inserted into the instrument, with the label side up and the arrows facing into the instrument.
2. Plug the instrument line cord into the instrument and into an appropriate grounded AC electrical outlet.
3. Install the roll of printer paper (refer to Section 6, "Periodic Maintenance").

4. Install the feed table insert (refer to Section 6, "Daily Maintenance," Step 5).
   NOTE: If you will be using a configuration of Bayer Diagnostics Reagent Strips that contains four tests or fewer, you must use a different feed table insert than the one supplied with the instrument. The *only* exception to this is with LIFESTIX™ Reagent Strips (not available in all countries). Most Reagent Strip configurations use the 4¼ inch insert, which can be identified by a circle (○) that is engraved on the end of the insert, near the calibration chip. Reagent Strips with four tests or fewer (except LIFESTIX) require a 3¼ inch insert, identified by a triangle (△). Refer to Section 9, SERVICE AND REPLACEMENT PARTS, to order the 3¼ inch insert.
5. Position the display screen for convenient viewing by raising it to the fully upright position, then lowering it to the desired position. (The screen must also be raised to prevent blocking of the ventilation openings on the instrument top.)

Interfacing To A Printer

The CLINITEK 100 can be interfaced to the CLINITEK® Form Printer or to most commercially available 80-column, continuous feed printers, via the printer port that is found on the rear of the instrument.

1. If interfacing to the Form Printer (Product No. 5255), obtain the interface cable that is supplied with the printer. Plug the appropriate end of the cable into the printer (parallel) port (labeled as ⎙) on the CLINITEK 100 instrument; plug the other end of the cable into the printer.
2. If interfacing to an 80-column printer, the interface cable must be obtained separately. Refer to Addendum I, "COMPUTER AND PRINTER INTERFACE," for the pin specifications for the female connector. The other end of the cable will be dependent upon the particular printer. Appropriate cables are available at most retail computer stores. Plug

the appropriate end of the interface cable into the printer (parallel) port (labeled as ⊚) on the CLINITEK 100; plug the other end into the printer.

3. Carefully read the operating manual that accompanies the printer and become familiar with its operation before using.

Interfacing To A Computer

The CLINITEK 100 can also be interfaced to a host computer via the EIA-232-D (serial) port. The specifications for interfacing to a computer are found in Appendix I, "COMPUTER AND PRINTER INTERFACE." Plug the appropriate end of the interface cable into the EIA-232-D port on the CLINITEK 100; plug the other end into the appropriate port on the computer, following the instructions given with the computer.

Initial Instrument Check

After the CLINITEK 100 has been properly installed, perform the following Initial Instrument Check. The actions that should occur during instrument operation are described in this check. If problems occur during this procedure or if an error is displayed, refer to Section 7, TROUBLESHOOTING.

1. Turn the instrument power *on* by placing the power switch (on the back of the instrument) to the ON position. Be sure the display screen has been raised to an upright position; adjust the contrast, if necessary, using the dial found on the right side of the screen. The reagent strip feed table will automatically move out to the "load" position and the display will show:

```
CLINITEK 100

CALIBRATING INSTRUMENT - PLEASE WAIT
```

The instrument will then perform a calibration and self-test procedure, which consists of checking the position of the feed table, checking the light intensity of the LEDs, and calibrating the LEDs. Once the procedure is complete, the display will change to, for example:

```
Multistix 10 SG                    10-22-91
                                   03:30 pm

                    CLINITEK 100
                    Version F3.00

MENU                                   START
```

NOTE: The name of the Reagent Strip being displayed must correspond to the name of the Bayer Diagnostics Reagent Strip to be used. Use of any other strip will cause erroneous results. If the name being displayed is not correct for the strip being used, contact your Bayer Diagnostics representative or office.

2. Inspect the feed table insert. The insert must be fully inserted into the feed table. The strip holding channel must be free of dust and foreign matter. For detailed information, see Section 6, "Daily Cleaning."

3. Press the ◇ (START) key. The display will change to the Test Screen:

```
Seq No: 1-001        Color:    Yellow
I.D.                 Clarity:  Clear

                  Place Strip on Table
```

After approximately 10 seconds, the feed table will move inward and stop in the "storage" position. With no Reagent Strip on the table, the feed table will return to the "load" position and the display will show the message "Caution: INSTRUMENT WARNING . . . STRIP MISSING Press Any Key to Continue . . ."

4. Once any key is pressed, the display will return to the Main Menu (described in Section 2).

5. Carefully immerse a fresh Bayer Diagnostics Reagent Strip into a negative control urine, such as CHEK-STIX® Negative Control Strips solution. Remove the strip immediately; while removing, run the edge of the entire length of the Reagent Strip against the side of the tube to remove excess urine. Press ◈ at the same time the strip is removed; the display will again change to the Test Screen (shown in Step 3 above).

6. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 3-2). *Do not draw the strip across the towel; touch the edge only.*

7. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing ◈ (Figure 3-3). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Following a brief delay, the feed table will move into the instrument to allow the Reagent Strip to be read.
   NOTE: Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.**

8. Press the ↵ key 3 times to bypass the displays for I.D., color, and clarity.

9. The test results will be shown on the display as each test is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte test is read (approximately 10-20 seconds later, depending on which Reagent Strip is being used); the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
   NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

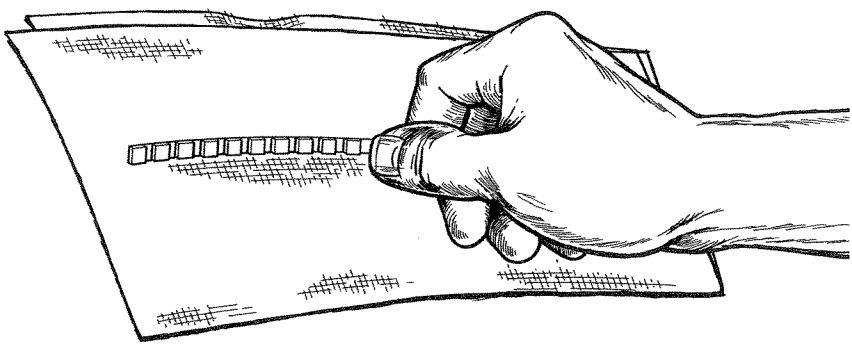


Figure 3-2
Blotting the Reagent Strip

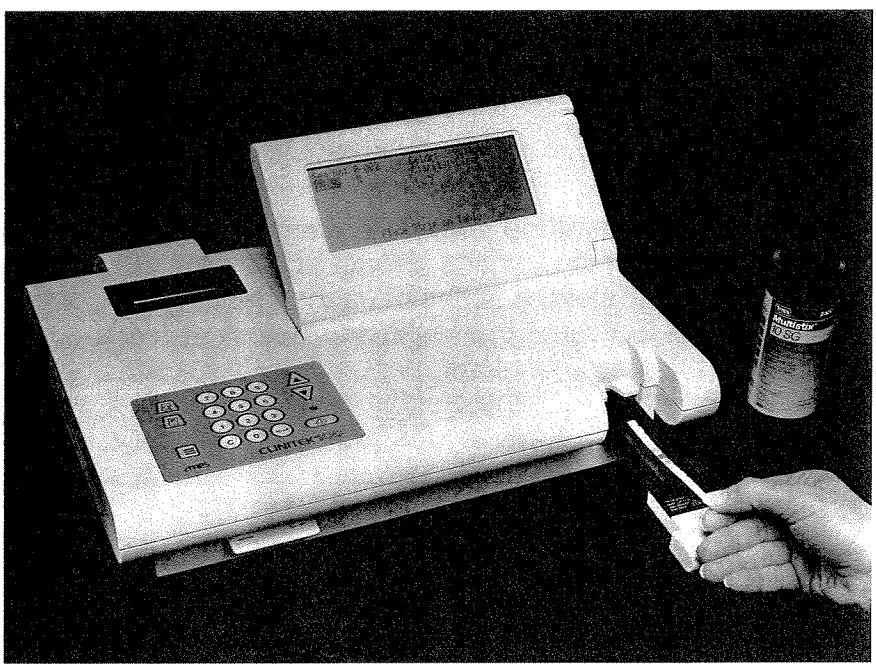


Figure 3-3
Placing Reagent Strip on Feed Table

10. Once all results are displayed, they will be printed by the internal printer.

11. The instrument should produce a result for each reagent area that is within the limits given in the package insert for the control urine, as shown on the following example:

```
Seq No: 0-001          Color:   Yellow
I.D.                   Clarity: Clear

GLU Negative       PRO Negative
BIL Negative       URO 0.2 EU/dL
KET Negative       NIT Negative
SG  1.010          BLO Negative          MENU
pH  6.0            LEU Negative          START
```

12. If the instrument does not display the expected values for the reagent areas selected, refer to Section 7, TROUBLE-SHOOTING, for customer service information.

13. Remove and discard the used Reagent Strip.

14. Press the [≡] key (MENU) to return the display to the Main Menu. If necessary, set the desired beginning sequence number, as described in Section 2, EXPLANATION OF SOFTWARE AND ROUTINES, Part A, Step 1. Then enter the "Instrument Setup Routine" and select the desired operating parameters, as described in Part B of the same section. After all parameters have been set, highlight "Status" on the Setup Menu and press [↵] to display the instrument setup parameters. Record and save a copy of these parameters, in case a replacement instrument must be set up.

15. With satisfactory completion of the Initial Instrument Check and selection of the desired operating parameters, the CLINITEK 100 instrument is ready for routine testing.

16. Before beginning normal instrument use, carefully review the following sections to become familiar with operating techniques and instrument cleaning requirements:
    Section 4—OPERATING INSTRUCTIONS
    Section 6—CARE OF THE INSTRUMENT

17. Locate the serial number on the back of the instrument. Write the installation date and the instrument serial number on the Warranty Registration Card packed with the instrument. Also write the installation date and serial number on the Manufacturer's Warranty page at the end of this manual and in the "Preservice Checklist" in Section 9. Completely fill out the Warranty Registration Card and mail.

OPERATING INSTRUCTIONS

Following initial installation (Section 3), the CLINITEK® 100 Urine Chemistry Analyzer can be operated on a day-to-day basis by the following procedures. Carefully read Section 2 (EXPLANATION OF SOFTWARE AND ROUTINES) for a complete description of the displays, prompts, and operating sequences before beginning any testing.

Activating the CLINITEK 100 Instrument

Ensure that the Program Card is firmly in place. Turn the CLINITEK 100 instrument *on,* if necessary. Be sure the display screen is in an upright position; adjust the contrast, if necessary, using the dial on the right side of the screen.

The feed table will automatically move out to the "load" position and the display will show the message "Calibrating Instrument Please Wait." The instrument will automatically perform a calibration and self-test procedure; upon successful completion of the procedure, the display will change to the Main Menu; for example:

```
Multistix 10 SG                    10-22-91
                                   09:30 am

                  CLINITEK 100
                  Version F3.00


MENU                                  START
```

IMPORTANT: The name of the Reagent Strip being displayed must correspond to the name of the Bayer Diagnostics Reagent Strip for Urinalysis that is to be used. Use of any other strip will cause erroneous results. If the names do not agree, contact your Bayer Diagnostics representative or office to select the correct Reagent Strip.
NOTE: The CLINITEK 100 may be used immediately after it is turned *on* and the self-test is complete. No warm-up time is required.

Inspection of Reagent Strip Feed Table

Inspect the feed table and feed table insert for cleanliness and correct positioning. If either appears dirty, remove the feed table insert and clean as described in Section 6, "Daily Cleaning."

CLINITEK 100 Instrument/Reagent Strip Performance Check

The following procedure provides a check on Reagent Strip performance and instrument operation. This procedure is intended to provide confidence that Reagent Strips are reacting and being read properly. Errors resulting from user techniques can also be detected. It is suggested that Performance Checks be made under the following conditions:

a. At the start of the day's run;
b. When using a new bottle of Reagent Strips;
c. When changing instrument operators;
d. Whenever test results are in doubt.

CHEK-STIX® Positive and Negative Control Strips for Urinalysis are available for CLINITEK 100 Instrument/Reagent Strip Performance Checks. These Control Strips provide positive, negative, or defined reactions when used with Bayer Diagnostics Reagent Strips for Urinalysis. Alternatively, a urine specimen from a normal, healthy individual can be used as a negative specimen. Additional information on CHEK-STIX Positive and Negative Control Strips can be found in Section 5 of this manual and in the package insert.

To perform the CLINITEK 100 Instrument/Reagent Strip Performance Check procedure, proceed as follows:

1. Prepare the appropriate CHEK-STIX solution by following the directions found in the package insert or on the bottle label.
   NOTE: Use freshly prepared CHEK-STIX solution only. See package insert or bottle label for stability information.
2. Set the appropriate sequence number, if needed, through the Main Menu ("Set Sequence No."). If desired, use the "C" prefix for the test by selecting the "Control Sample" prompt in the Main Menu.

3. Completely immerse all reagent areas of a Bayer Diagnostics Reagent Strip in the CHEK-STIX solution. Remove the Reagent Strip immediately; while removing, run the edge of the entire length of the Reagent Strip against the side of the container to remove excess CHEK-STIX solution. Press ◇ (START) at the same time the strip is removed; the display will change to the Test Screen, with the prompt "Place Strip on Table."

4. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 4-1). Do not draw the strip across the towel; touch the edge only.

5. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing ◇ (Figure 4-2). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.**

6. After a brief delay, the feed table will move into the instrument. The test results will be displayed as each reagent area is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte result is obtained; the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
   NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

7. Press ↵ up to 3 times to bypass the I.D., Color, and Clarity prompts if they are being displayed. Once all results are displayed, they will be printed by the internal and/or external printer (depending upon the parameters selected in the Instrument Setup Routine).

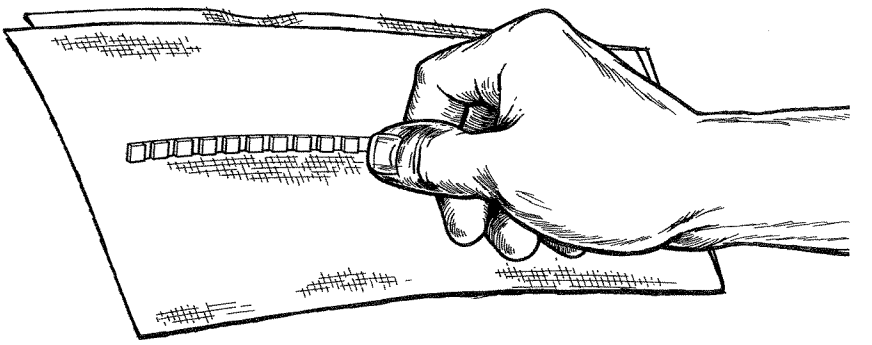


Figure 4-1
Blotting the Reagent Strip

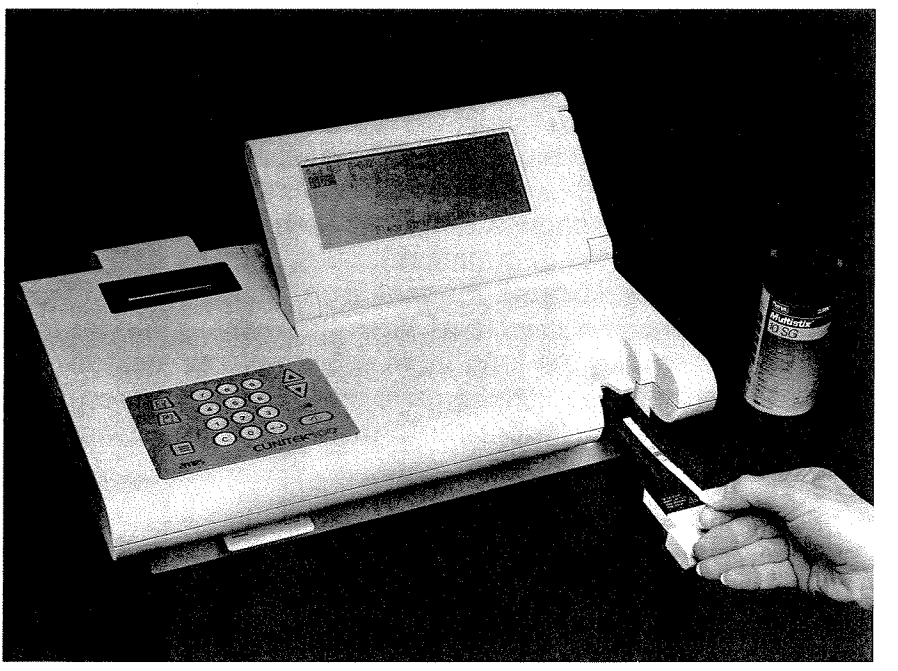


Figure 4-2
Placing Reagent Strip on Feed Table

8. Remove and discard the used Reagent Strip.
9. The CHEK-STIX solution should produce the values stated in the CHEK-STIX package insert.

If a CLINITEK 100/Reagent Strip Performance Check falls outside the stated values, the following sources of error may have occurred:

a. Improper technique or instrument setup. Check that the Reagent Strip being used corresponds to the Reagent Strip name given on the Main Menu display. Carefully repeat the Instrument/Reagent Strip Performance Check procedure as described above.
b. Deterioration of the Reagent Strip test areas due to exposure to light, ambient moisture or heat. Obtain a fresh bottle of the Bayer Diagnostics Reagent Strips being used and repeat the Instrument/Reagent Strip Performance Check procedure. If fresh Reagent Strips fail to give results within the expected values, proceed to Step c.
c. Deterioration of the CHEK-STIX solution. Prepare a fresh CHEK-STIX solution and repeat the Instrument/ Reagent Strip Performance Check procedure. If fresh solution fails to give results within the expected values, proceed to Step d.
d. Deterioration of the CHEK-STIX Control Strips. Obtain a fresh bottle of CHEK-STIX Control Strips and prepare a fresh CHEK-STIX solution. Repeat the Instrument/ Reagent Strip Performance Check procedure. If the solution from the fresh Control Strip fails to give results within the expected values, proceed to Step e.
e. CLINITEK 100 instrument malfunction. Perform an Initial Instrument Check procedure (see Section 3). If the Initial Instrument Check or the Instrument/Reagent Strip Performance Check procedures cannot be successfully completed and an instrument malfunction or Reagent Strip problem is suspected, see Section 7, TROUBLE-SHOOTING, or contact the Customer Service Department for assistance (see Section 9 for further customer service information).

Procedure for Urine Analysis

Using the CLINITEK 100 Instrument/Reagent Strip System

1. Set the appropriate sequence number, if needed, through the Main Menu ("Set Sequence No."). To run a STAT specimen, highlight the "STAT Sample" option in the Main Menu and press ↵.
2. Completely immerse all reagent areas of a Bayer Diagnostics Reagent Strip in *fresh,* well-mixed, uncentrifuged urine. Remove the Reagent Strip *immediately;* while removing, run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine. Press the ◇ key on the instrument at the same time the strip is removed. The display will change to the Test Screen, showing the sequence number (Seq No.) of the strip being tested, as well as the fields for entry of the identification number (I.D.), color, and clarity, if these options were selected through the Instrument Setup Routine.
3. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 4-1). Do not draw the strip across the towel; touch the edge only.
4. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing ◇ (Figure 4-2). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.** After a brief delay, the feed table will move into the instrument.

5. If the options for using ID numbers and/or color/clarity have been selected, there are several opportunities to enter or confirm the requested information. The easiest times to enter data are:
   - immediately after the strip is placed onto the feed table,
   - while waiting for the leukocyte result; and
   - after all results have been displayed.

   Data can also be entered at almost any time during the testing cycle; however, the keyboard will lock when the instrument is actually taking a reading, so any key that is pressed during this time will not respond immediately. Enter the requested information as instructed in Steps 6-8 below.

6. a. **If ID numbers have been loadlisted,** the first number in the list will be displayed in the ID number field. If the number being displayed agrees exactly with the specimen being tested, press [↵] . If it does not agree, either:
      i. Enter the correct ID number using the numeric keyboard, directly replacing the number being displayed, or
      ii. Press [C] (CLEAR) to erase the number. If the [C] key is used, the ID number that was initially displayed will be lost and will be replaced by the next number in the load list. Repeat Step 6-a to enter the correct ID number.

      NOTE: As long as a load list is present in the instrument's memory, the abbreviation "LDLST" (for "Loadlist") will appear on the display screen. When the final ID number has been removed from the load list, "LDLST" will no longer be displayed.

   b. **If there are no ID numbers in a load list,** either because they have all been tested or because a load list was not present initially, enter the ID number using the numeric keyboard. Up to 10 digits can be entered. When the number has been correctly entered, press [↵] . If an error is made, press [C] (CLEAR) and enter the number again.

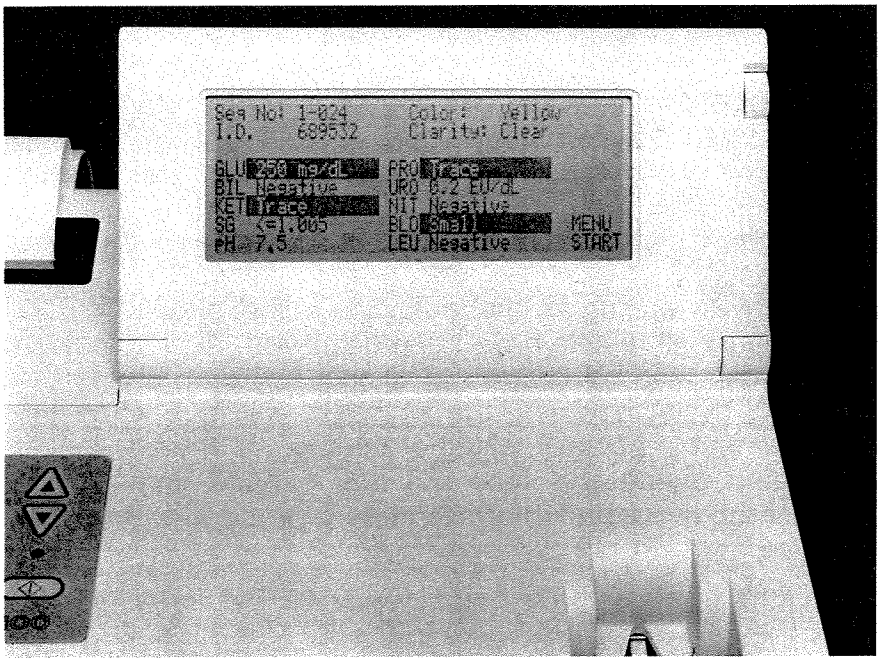


Figure 4-3
Display of Results

```
#1-024      01-29-92
I.D. 689532
Color:   Yellow
Clarity: Clear

*GLU 250 mg/dL
 BIL Negative
*KET Trace
 SG  <=1.005
 pH  7.5
*PRO Trace
 URO 0.2 EU/dL
 NIT Negative
*BLO Small
 LEU Negative
```

Figure 4-4
Printout of Results

7. The cursor will move to the Color field, where the default color of "Yellow" will be displayed. To change the displayed value, press the ▼ or ▲ keys until the desired description is being displayed, then press ↵ . There are eight descriptions for Color: Yellow, Dk Yellow, Straw, Amber, Green, Orange, Red, and Other.

8. The cursor will move to the Clarity field, where the default value of "Clear" will be displayed. Change the displayed value, if necessary, by pressing ▼ or ▲ until the desired description is being displayed, then press ↵ . There are five descriptions for Clarity: Clear, Sl Cloudy, Cloudy, Turbid, and Other.

9. The test results will be displayed as each reagent area is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte result is obtained; the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
   NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore, the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

10. Once all results are displayed, including entry of the specimen ID, color, and clarity if these options were selected, they will be printed by the internal and/or external printer (depending upon the parameters selected in the Instrument Setup Routine). While results are being printed, the keyboard is locked. Once printing is complete, however, the display of results will also list the active keys of "MENU" and "START" (Figure 4-3). Refer to Figure 4-4 for an example of the internal printout with abnormal results flagged.

NOTE: If the ID and/or color/clarity fields are being displayed, this information *must* be entered before the test results will be printed and before another strip can be run. The ◇ key will not respond until *all* results for the current test (including ID, color, and clarity) have been entered and printed.

11. Remove and discard the used Reagent Strip.

12. a. To run another test, dip a fresh strip into the next specimen and press ◇ as soon as the strip is removed from the specimen; or
    b. Press ☰ to return to the Main Menu.

    IMPORTANT: Do not attempt to test a new specimen until "START" is being displayed.

13. **To run a STAT sample,** return to the Main Menu (by pressing ☰) *before* beginning the testing sequence for the STAT sample. Highlight "STAT Sample" in the Main Menu and press ↵ to change the prefix of the sequence number to "S." Analyze the STAT sample in the normal manner. The operating sequence is identical to that previously described; however, if a load list is present in the instrument's memory, display of the loadlisted ID numbers will be interrupted for the STAT sample, allowing the STAT ID number to be entered. After the results have been printed, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted.

14. If an error is detected by the instrument, an appropriate error message will be displayed. Should this occur, refer to Section 7, TROUBLESHOOTING, for the probable cause and remedy of the error condition.

Operating Notes

1. To keep the feed table insert and its strip holding channel clean, wipe the channel with a damp, absorbent tissue as frequently as necessary to prevent excessive accumulation of urine. Also, wipe the insert after each batch is completed. To prevent the insert from misaligning, press against it with the thumb while wiping. See Section 6, CARE OF THE INSTRUMENT, for complete information on cleaning the feed table and feed table insert.
2. The instrument does not detect when the internal printer is out of paper and therefore will continue printing results even if there is no paper. However, the last several feet of paper on the roll contains a pink edge; the roll should be changed when this appears. Should any results be lost, they can be reprinted by entering the "Data Recall" routine from the Main Menu and pressing the key to print the desired files as each is displayed.
3. When the sequential ID number reaches "999," the next number assigned will be "001"; the prefix number will not change. For example, sequence number 1-999 will become 1-001 with the next specimen.
4. If you wish to clear a load list (partial or full) from the instrument memory, enter the **Instrument Setup** Routine and turn *off,* then back *on,* the option to use ID numbers. The load list will be erased to allow entry of a new list.

When Testing is Complete

1. When all testing has been completed, clean the feed table and feed table insert and inspect the white calibration chip, as described under "Daily Cleaning" in Section 6, CARE OF THE INSTRUMENT. If the insert is excessively dirty, clean as described under "Periodic Cleaning" in Section 6.
2. Gently push the table in to the "storage" position.
   NOTE: No Reagent Strip should be on the feed table when the instrument is not in use.
3. The instrument may be left *on* when it is not in use.

Figure 5-1
CHEK-STIX® Control Strips for Urinalysis

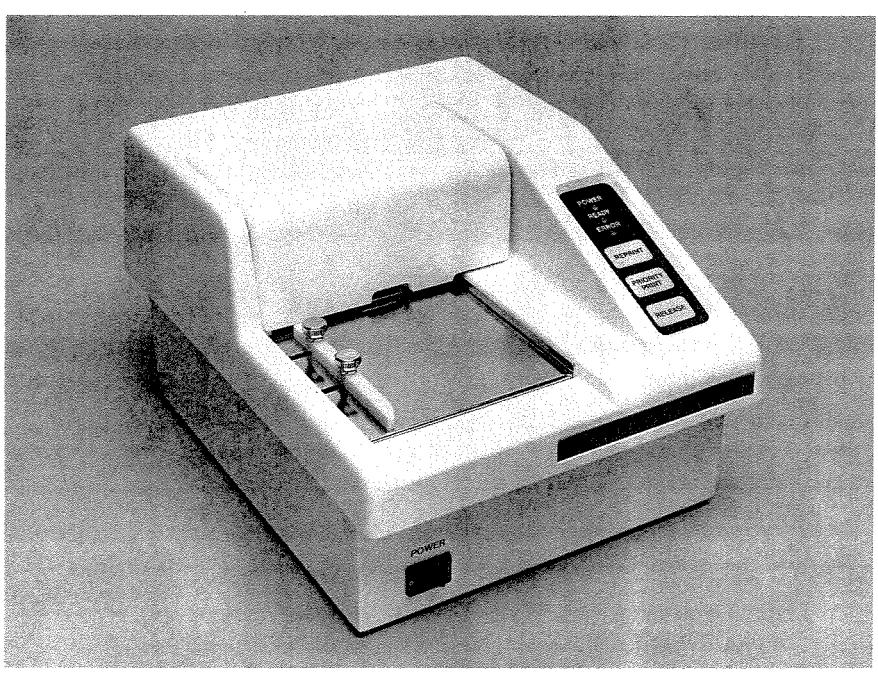


Figure 5-2
CLINITEK® Form Printer

ACCESSORIES

CHEK-STIX® Positive and Negative Control Strips for Urinalysis

Combo Pak (Product Code No. 1364)
Positive Control Strips (Product Code No. 1360)
Negative Control Strips (Product Code No. 1365)

CHEK-STIX® Positive and Negative Control Strips for Urinalysis (Figure 5-1) provide a performance check for the CLINITEK® 100 Instrument/Reagent Strip System. CHEK-STIX Control Strips provide confidence that the Reagent Strips are reacting and being read properly. Errors resulting from user technique can also be detected.

CHEK-STIX Control Strips are reconstituted in distilled water to make up a CHEK-STIX control solution. Instructions are included in the package insert and on the bottle label, and test results that should be obtained are listed in the package insert. The Control Strips are available as a Combo Pak, which contains one bottle each of the Positive Control Strips and Negative Control Strips (25 strips/bottle). The Positive Control Strips and Negative Control Strips are also each available as separate products (one bottle of 25 strips).

CLINITEK® Form Printer

(Product Code No. 5255)

The CLINITEK® Form Printer (Figure 5-2) is available from Bayer Diagnostics for use with the CLINITEK 100 instrument. It can be interfaced to the instrument and all results then printed onto multi-copy forms. Three-copy forms (Product Code No. 5163) and replacement ribbon cartridges (Product Code No. 5256) are available from Bayer Diagnostics for use with the printer. The printer includes an interface cable for use with the CLINITEK 100 instrument.

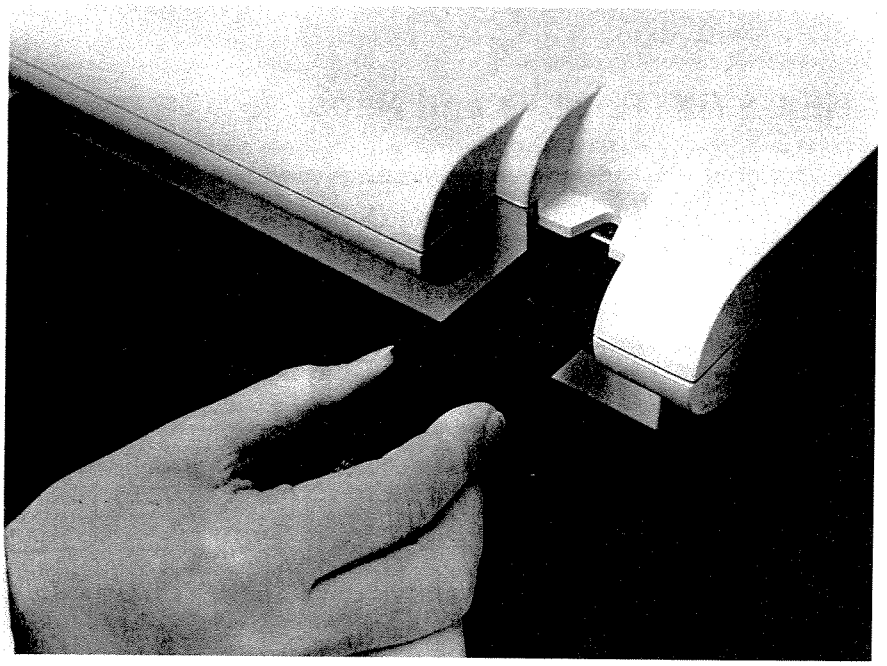


Figure 6-1
Removing the Feed Table Insert

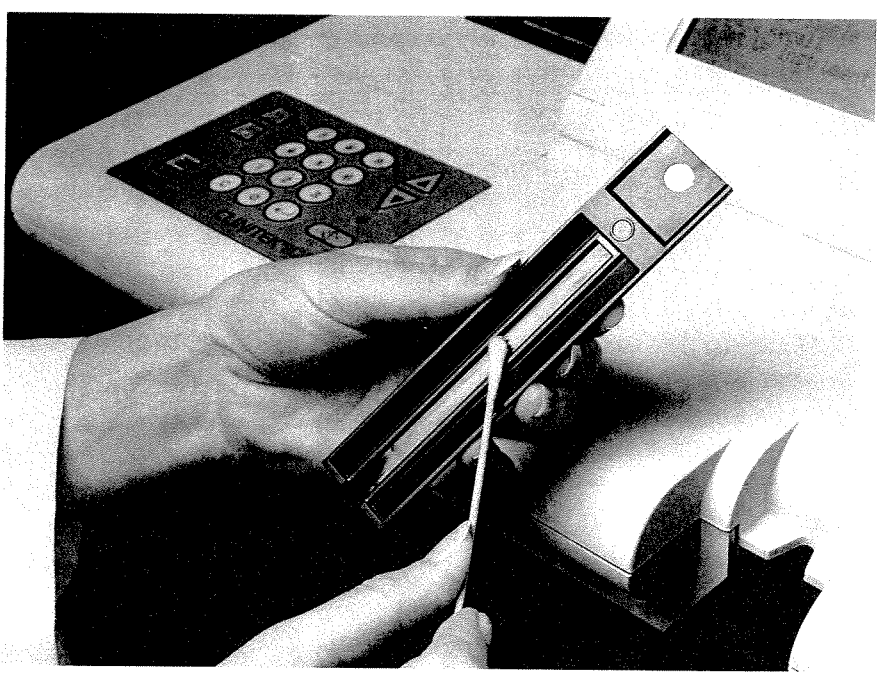


Figure 6-2
Cleaning the Feed Table Insert

CARE OF THE INSTRUMENT

General Cleaning

Keep the exterior of the instrument free of dust at all times. If needed, the exterior may be cleaned using a damp cloth and a mild detergent. Do not use any type of solvent on any part of the instrument. Do not use any type of lubrication on the instrument; use of oil, grease, silicon spray, or any other lubrication may damage the instrument.

The display screen may be cleaned as needed by wiping with a soft, nonabrasive cloth that has been dampened with glass cleaner. Do not spray the glass cleaner directly on the screen. Do not use laboratory wipes, such as Kimwipes®, as they may scratch the screen.

Daily Cleaning

The feed table and feed table insert must be kept clean to obtain the best results with the CLINITEK® 100 Instrument/ Reagent Strip system. At the end of each day's use, the instrument's white plastic calibration chip, located on the feed table insert, and the reagent strip holding channel should be cleaned. To clean the feed table insert, perform the following:

1. Turn the CLINITEK 100 instrument *on*. The feed table will move out from the "storage" position to the "load" position. (If the instrument is already *on* but the feed table is in the "storage" position, it can be gently pulled out to the "load" position.)
2. **To remove the feed table insert from the feed table:** Grasp the front end of the insert on each side with the thumb and one finger. Apply a counter pressure with the palm of the hand against the feed table and gently pull the insert outward (Figure 6-1). After the insert is completely exposed, lift the front end of the insert up and off the table.
3. Clean the insert using a cotton-tipped applicator stick or other suitable absorbent material wetted with distilled water. Thoroughly swab the strip holding channel area until it is clean (Figure 6-2). Inspect the surface of the white plastic calibration chip for dust, foreign material, scratches, or scuffs. If necessary, gently wipe the calibration chip with

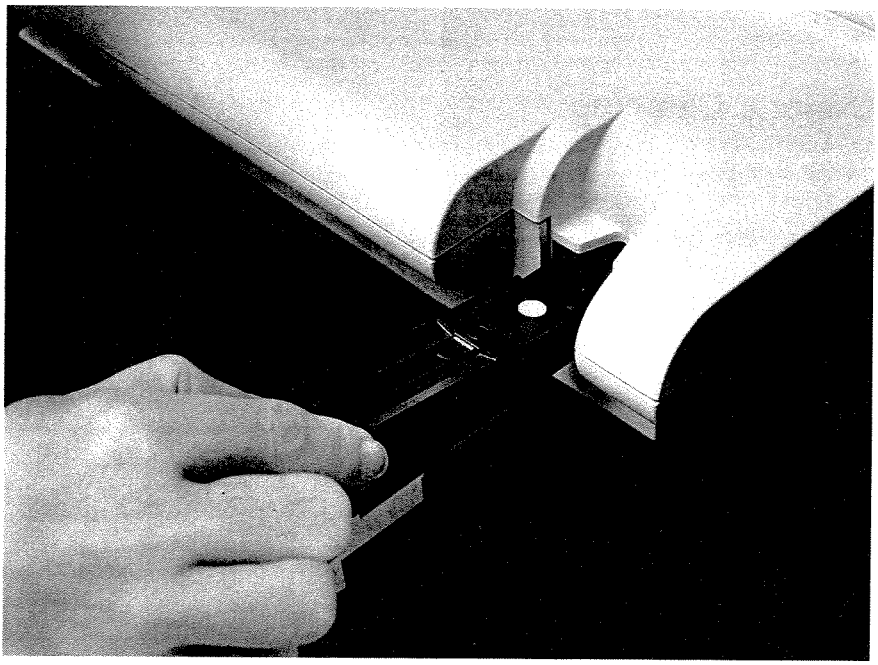


Figure 6-3
Replacing the Feed Table Insert

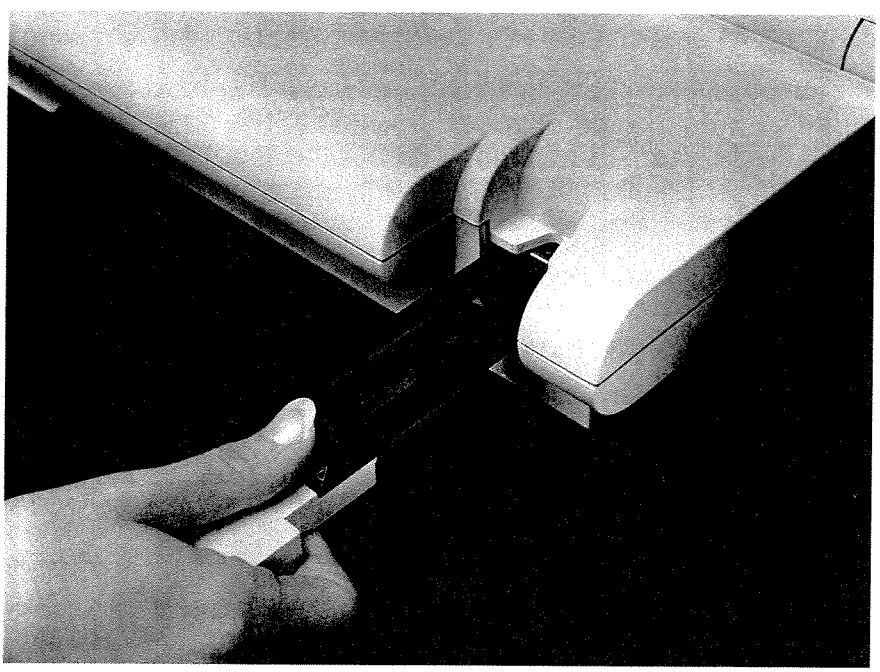


Figure 6-4
Replacing the Feed Table Insert

a cotton-tipped applicator stick wetted with distilled water. Allow the calibration chip to air dry before using. Make sure no foreign particles remain on its surface. If the calibration chip cannot be cleaned or is scratched or scuffed, replace the feed table insert (see Section 9, "Replacement Parts"). **CAUTION: Do not use any material that will scratch the feed table insert or the plastic calibration chip. Do not use solvents of any kind to clean the calibration chip.**

4. Wipe the feed table surface and feed table mounting groove with a damp cloth. Wipe the feed table dry with an absorbent tissue.

5. **To replace the feed table insert in the feed table:** Hold the feed table insert in the same manner as when it was removed (holding it by the end opposite the calibration chip). With the front end angled upwards, insert the calibration chip end about midway onto the feed table (Figure 6-3). *Slide the insert in while lowering the front end until* the insert is laying flat against the table and resistance is felt. Then place the thumb against the front edge of the insert and two fingers against the underside of the feed table. Apply a counter-pressure to the feed table while pressing the insert firmly inward (Figure 6-4). The insert is properly positioned in the feed table when the front edge is flush with the retaining rails of the feed table.

6. After replacing the feed table insert, the LEDs must be recalibrated. To ensure this occurs, turn the instrument *off,* wait several seconds, then turn it *on* again before testing additional samples.

CAUTION: If the calibration chip or a contact point becomes damaged, the feed table insert should be replaced.

Disinfection

The only part of the CLINITEK 100 instrument that comes into contact with the urine specimen is the feed table insert. To disinfect the insert, perform the following procedure:

1. Remove, clean, and dry the feed table insert as directed in "Daily Cleaning," Steps 1 to 4.
2. Prepare one of the following solutions for use in disinfection:
   a. 2% glutaraldehyde solution–Cidex™ * (used full strength) is a commercially available product that is acceptable for use. Refer to the labeling accompanying this disinfection product for complete instructions on its use.
   b. 0.25% sodium hypochlorite solution–dilute 5 mL of 5% sodium hypochlorite (e.g., Clorox®** Bleach) into 95 mL of water for a 1:20 dilution.
   c. Isopropyl alcohol (70%–85%), undiluted.
3. Fill a tall, narrow container to a depth of 4 inches (10 cm) with the disinfection solution.
4. Immerse the feed table insert into the disinfection solution **so the white plastic calibration chip remains above the liquid level.**
   CAUTION: Do not allow the disinfection solution to come in contact with the white plastic calibration chip, located on the feed table insert, or with any other portion of the feed table or instrument.

*Cidex™ is a trademark of Surgikos, Inc., Arlington, Texas.
**Clorox® is a registered trademark of The Clorox Company, Oakland, California.

5. Allow the feed table insert to remain in the solution for 10 minutes.
6. Remove the feed table insert and rinse thoroughly with distilled water to remove any residual solution.
7. Wipe the feed table insert dry with an absorbent tissue.
8. Replace the feed table insert in the feed table, as instructed in Steps 5 and 6 of the "Daily Cleaning" procedure.

Periodic Maintenance

Changing the Paper:

1. Lift the cover on the internal printer by pressing in on the lever on the back of the printer cover and lifting up on the cover (Figure 6-5). Remove the cover by pulling it towards the back of the instrument.
2. Remove the used paper roll core.
3. Place a new roll of paper into the printer, with the paper unrolling from beneath.
4. Feed the paper under the roller, as shown in the diagram in the printer, and advance the paper through the printer by rotating the knob on the right side of the printer (Figure 6-6). If the paper does not catch immediately, gently feed the paper into the roller while continuing to rotate the knob. To make insertion easier, be sure the leading edge is a clean, straight cut; trimming the paper to a point may also assist in easier insertion.
5. Allow 2-3 inches of paper to advance through the roller, then feed the paper through the opening on the printer cover. Place the lip of the cover under the ledge on the instrument opening and close the cover. Press down firmly on the back of the cover until it snaps into place.

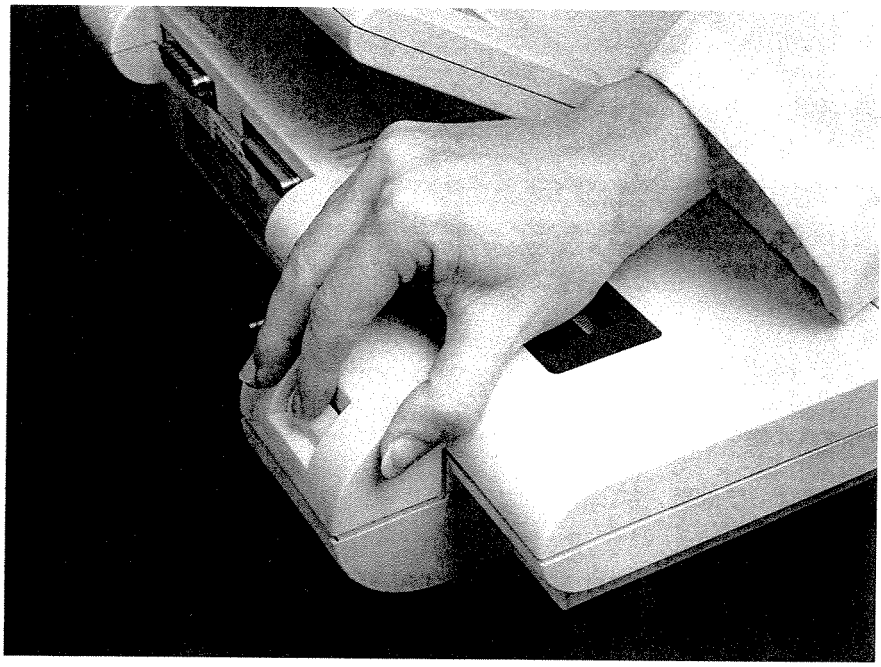


Figure 6-5
Removing the Printer Cover

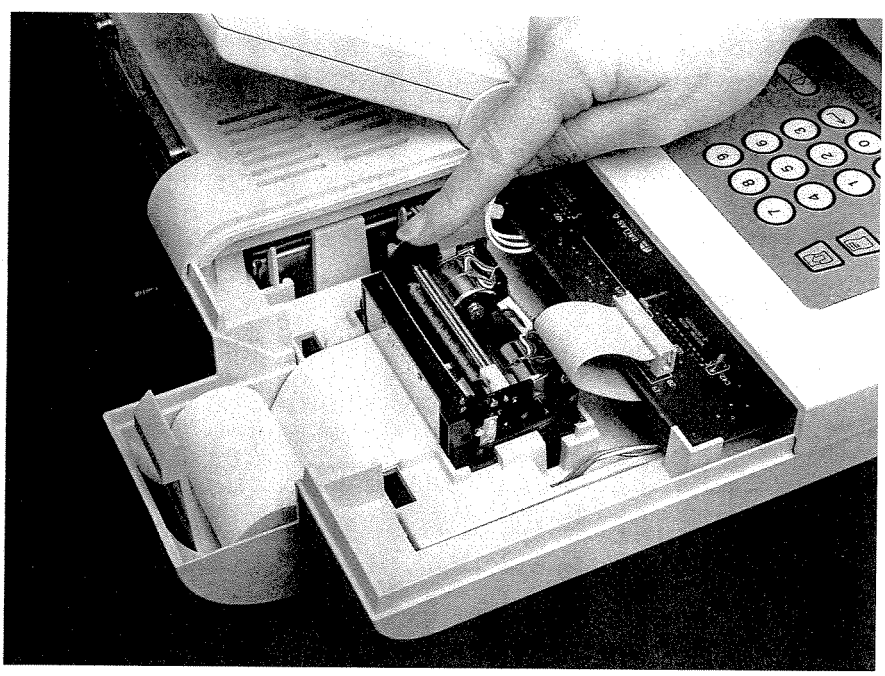


Figure 6-6
Installing the Paper

Periodic Cleaning:

If the feed table insert becomes excessively dirty and cannot be adequately cleaned as described in the "Daily Cleaning" procedure, the following procedure should be used:

1. Remove the feed table insert from the feed table, as described in Step 2 of the "Daily Cleaning" procedure.
2. Wipe the strip holding channel of the feed table insert with 0.1 N sodium hydroxide (NaOH) using a cotton-tipped applicator stick or other suitable absorbent material. Thoroughly swab the channel area until it is clean. **Do not wipe the white calibration chip with the NaOH.**
   CAUTION: Do not use any material that will scratch the feed table insert. Do not allow the NaOH to come in contact with the white plastic calibration chip or with any other portion of the feed table or instrument.
3. Rinse the feed table insert channel thoroughly with water to remove any residual NaOH.
4. Wipe the feed table surface and feed table mounting groove with a damp cloth. Wipe the feed table dry with an absorbent tissue.
5. Replace the feed table insert in the feed table, as instructed in Steps 5 and 6 of the "Daily Cleaning" procedure.

TROUBLESHOOTING

General Information

Error messages may be shown on the display of the CLINITEK® 100 Urine Chemistry Analyzer to alert the operator of an operational or instrument problem. This section of the manual lists the various errors that may be displayed, along with probable causes and recommended remedies, so that many isolated problems can be quickly corrected.

If additional assistance is required concerning an instrument problem, complete the "Preservice Checklist" in Section 9, SERVICE AND REPLACEMENT PARTS, then contact the Customer Service Department of Bayer Corporation, Diagnostics Division, by calling toll free 1-800-348-8100.

For problems concerning the Bayer Diagnostics Reagent Strips for Urinalysis or CHEK-STIX® Control Strips for Urinalysis, refer to the appropriate package insert for information that may help solve the problem, or contact the Customer Service Department.

For Customer Service outside the United States, contact the nearest Bayer Diagnostics office for information and assistance.

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
Cal Chip Read Error (HIGH) or (LOW)	The reading taken on the calibration chip was above or below the specified limits because:	
	1. The calibration chip is dirty.	1. Clean the feed table insert and calibration chip, as directed in Section 6, "Daily Cleaning."
	2. The feed table insert is not properly positioned on the feed table.	2. Reinstall the insert so it is properly positioned; recalibrate the instrument (turn the power *off,* wait several seconds, then turn it back *on*).
	3. The ambient room temperature has changed significantly since the instrument was turned *on.*	3. Recalibrate the instrument (turn the power *off,* wait several seconds, then turn it back *on*).
Calibration Edge Error	Error in calibration because:	
	1. Feed table was bumped during the calibration procedure.	1. Be sure not to bump or jar the feed table during calibration. Turn the instrument *off,* wait several seconds, then turn it back *on* to recalibrate the instrument.
	2. Feed table insert is not properly positioned on the feed table.	2. Reinstall the insert so it is properly positioned; recalibrate the instrument (turn the power *off,* wait several seconds, then turn it back *on*).
	3. Instrument malfunction.	3. Recalibrate the instrument (turn the power *off,* wait several seconds, then turn it back *on*). If error repeats, contact Customer Service.

Calibration Error (HIGH) or (LOW)	The reading taken during calibration was above or below the specified limit.	Recalibrate the instrument (turn the power *off,* wait several seconds, then turn it back *on*). If error message repeats, contact Customer Service.
HARDWARE ERROR	Instrument malfunction	Contact Customer Service.
MEMORY FULL	The internal memory of 100 records is full (occurs only when computer port is *on*).	Transmit some or all of the records to the host computer to empty the memory (the computer must be turned *on* and request transmission); alternatively, clear the memory or turn *off* the computer port through the **Instrument Setup** Routine.
NO Computer Port Response	The computer port is not responding when requested to transmit data.	Check the computer interface cables; check the Baud rate selected through the **Instrument Setup** Routine. Request retransmission of the record. **CAUTION: Turning the computer port *on* or *off,* or changing the Baud rate, will clear the memory.**
NO DATA in Memory	There are no records stored in memory.	No strips have been run since either the memory was cleared or all records were transmitted to a host computer. **CAUTION: Turning the computer port *on* or *off,* or changing the Baud rate, will clear the memory.**

Revised 3/93

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
No LOAD LIST in Memory	There are no ID numbers stored in the load list.	No ID numbers have been downloaded from a host computer or all numbers in the load list have been run. **CAUTION: Turning the "Use ID Numbers" option *off* or *on* will clear the load list memory.**
Printer Error	1. Internal printer: a. Printer is not properly connected to either the power or interface cables. (This should occur *only* if the module has just been replaced.) b. Printer malfunction.	1. Internal printer: a. Remove the printer module and reconnect the cables, making sure both are securely connected (see Section 8). b. Turn printer *off* through **Instrument Setup** Routine and contact Customer Service for replacement and repair information.
	2. External printer: a. A form was not present in the Form Printer.	2. External printer: a. Be sure a form is in place in the Form Printer before the results are transmitted. Resend the last record by pressing the key after returning to the Main Menu.
	b. Printer is not turned *on* or is not "On-Line."	b. Be sure the printer is turned *on* and is "On-Line," ready to receive data, before transmitting records. Resend the last record by pressing the key after returning to the Main Menu.

	c. Interface cable is not properly connected.	c. Be sure the cable is plugged into the printer port on the CLINITEK 100 instrument and into the appropriate port on the printer. Resend the last record by pressing the key after returning to the Main Menu.
RAM Chip Failure	All memory within the RAM chip has been lost, either because the battery backup for the chip has failed or because the chip is faulty.	Turn the instrument *off,* wait several seconds, then turn it back *on.* Reset all instrument parameters to the correct strip configuration, time and date, etc. (all memory is lost with this error). If error repeats continuously, contact Customer Service.
STRAY LIGHT Warning	1. Excess ambient light was detected by the instrument during the reading cycle. 2. Instrument malfunction.	1. Do not place instrument where it is exposed to bright light (i.e., direct sun or a bright desk lamp). Rerun the specimen using a fresh Reagent Strip. 2. If error repeats continuously and the instrument is properly located away from sources of bright light, contact Customer Service.
STRIP MISSING	There is no Reagent Strip detected on the feed table; strip is missing or has not been properly positioned on the table.	Be sure the Reagent Strip is in place on the feed table before the table moves into the instrument for reading; be sure the tip of the strip is positioned against the end stop of the feed table.

Revised 7/95

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
Strip Placement Error	1. Reagent Strip is dry, upside down, or incorrectly positioned on the feed table.	1. Be sure the strip is properly positioned on the feed table, has been dipped in the urine or control solution, and is placed with the pads facing up.
	2. A configuration of Reagent Strips other than what is programmed to be read is being used (this error cannot always be detected).	2. Be sure the strip being used corresponds to the name of the Reagent Strip shown on the Main Menu. Use of any other strip may give erroneous results.
Table Position Error (IN) or (OUT)	1. The table was bumped or otherwise mispositioned while reading a Reagent Strip.	1. Retest the urine or control sample using a fresh Reagent Strip. Be sure not to bump or jar the feed table during the entire testing procedure.
	2. Instrument malfunction.	2. If error repeats continuously, contact Customer Service.
Table SENSOR Failure	Instrument malfunction.	Retest the urine or control sample using a fresh Reagent Strip. If error repeats, contact Customer Service.

MINOR REPAIR

The CLINITEK® 100 Urine Chemistry Analyzer is a self-contained instrument that is almost maintenance free. With proper care and use, the instrument should operate reliably with a minimum of operator attention. The only minor repairs that can be performed are the replacement of the feed table insert and replacement of the fuse. In addition, the modular printer can be removed from the instrument and replaced with a new printer. This section is provided as an aid in performing these minor repairs and functions. For any repairs other than those given in this section, refer to Section 9, SERVICE AND REPLACEMENT PARTS, for instructions on obtaining service for your instrument.

Replacement of Feed Table Insert

Tools Required:
None

Parts Required:
Feed Table Insert (4¼ inch—Part No. 95001086)

The feed table insert must be replaced if it has become damaged. Remove the insert that is in the instrument, as directed in Section 6, "Daily Cleaning," Step 2. Install the new insert, as directed in Steps 5 and 6 of the same section.

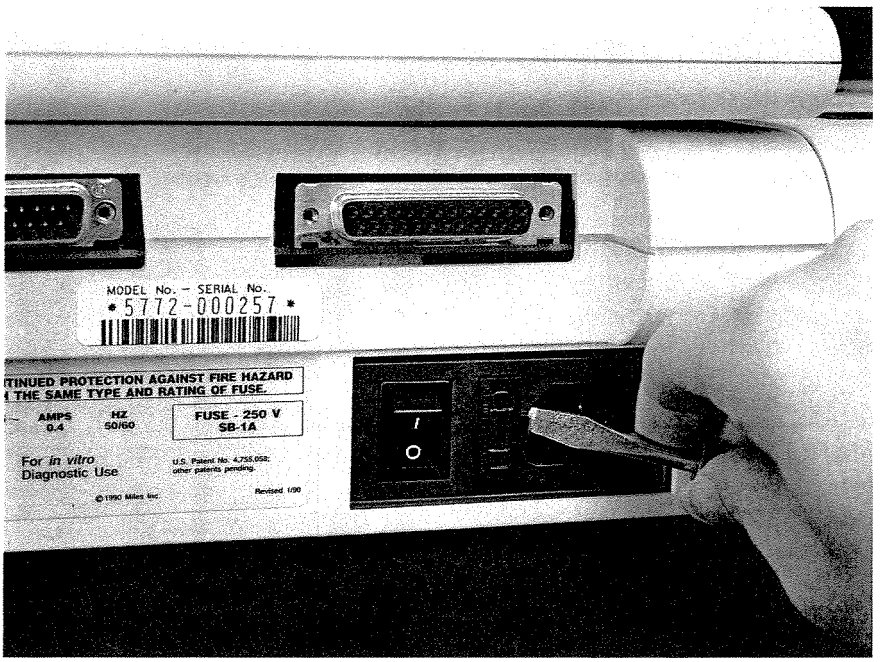


Figure 8-1
Opening the Fuse Cover

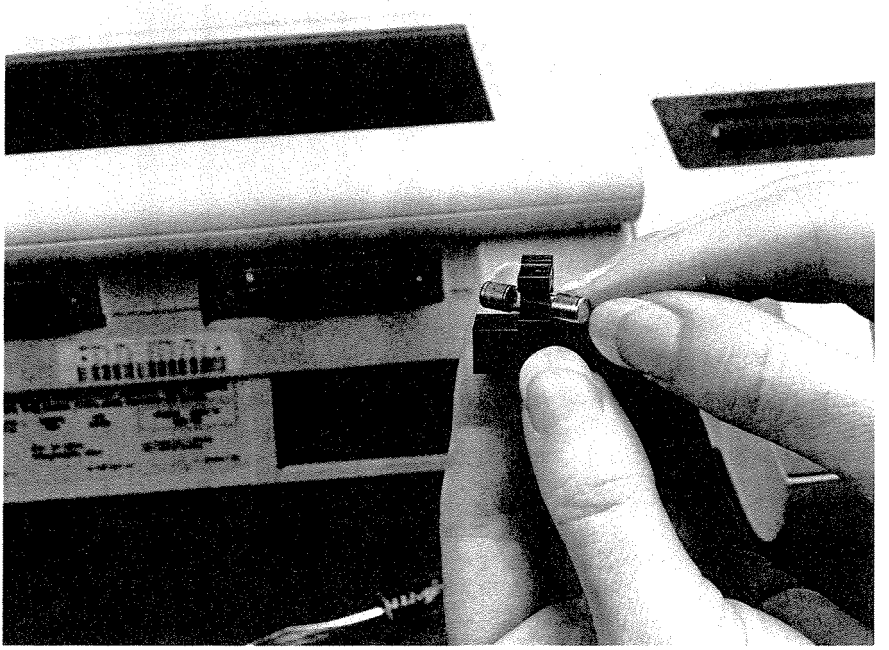


Figure 8-2
Replacing the Fuse

Fuse Replacement

Tools Required:
Screwdriver (narrow blade type, stubby)

Parts Required:
Instrument Line Fuse—
1.0 amp, Slo-Blo, 5x20mm (Part No. 40151108)
(for 115 VAC instruments)
*1.0 amp, Time Delay
(for 100 VAC instruments)
*2.0 amp, Time Delay
(for 220 or 240 VAC instruments)

Procedure:

1. **WARNING: TURN THE INSTRUMENT *OFF* AND REMOVE THE AC ELECTRICAL CORD FROM THE INSTRUMENT BEFORE REPLACING THE FUSE.**
2. Using a short, narrow-blade screwdriver (no more than about 2½ inches long), pry the fuse cover open (Figure 8-1). The entire fuse holder will now pull out of the instrument like a small drawer.
3. Pull the fuse out of the holder (Figure 8-2) and discard if blown.
4. Replace the defective fuse with an identical type fuse listed above.
   CAUTION: Use fuse of specified type and amperage rating only.
5. Replace the fuse cover into the instrument (with the closed side of the holder to the right). Press firmly on the cover until it snaps into place and is flush with the power module plate.

*For instruments located outside the United States, contact your local distributor for the appropriate fuse.

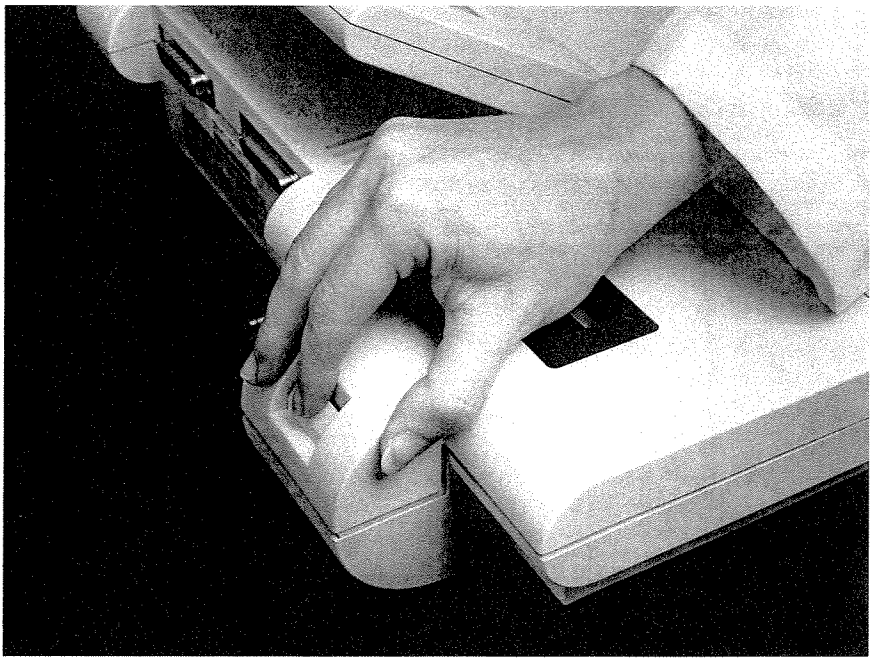


Figure 8-3
Removing the Printer Cover

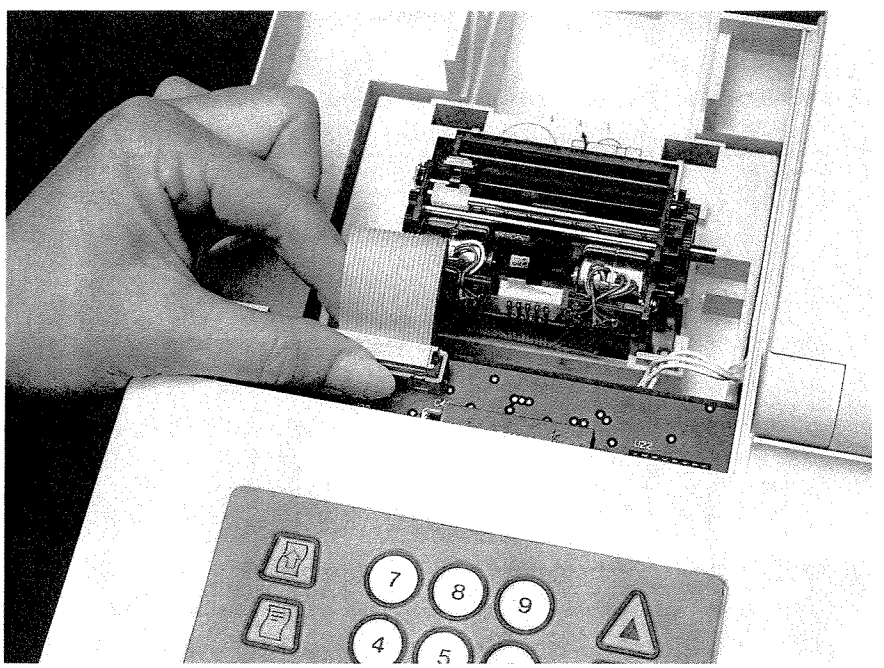


Figure 8-4
Printer Module Interface Cable

Removal and Replacement of Printer Module

Tools Required:
None

Parts Required:
Printer Module (Part No. 95001186)

Procedure:

CAUTION: When removing and replacing the printer module, do not touch the underside of the module; handle by the sides and top only. The lead pins underneath the module are sharp and may scratch, and static electricity from touching the pins may cause damage to the components.

1. **WARNING: TURN THE INSTRUMENT *OFF* AND REMOVE THE AC ELECTRICAL CORD FROM THE OUTLET.**
2. Lift the cover on the internal printer by pressing in on the lever on the back of the printer cover and lifting up on the cover (Figure 8-3). Remove the cover by pulling it towards the back of the instrument.
3. Remove the roll of paper from the printer by gently pulling the paper backwards from the print head (tear off any excess paper first), then lifting the roll out of the printer.
4. **To remove the printer module:**
   a. The printer is connected in the instrument by two different cables, a 14-pin interface cable for transferral of data (shown in Figure 8-4) and a 3-pin power cable that connects to a jumper cable via a keyed connector (shown in Figure 8-7). The jumper cable is tucked underneath the instrument cover and is most easily revealed *after* removing the printer module (Step 4-b). Disconnect the interface cable from the PC board by pulling straight up on the plug (Figure 8-4).

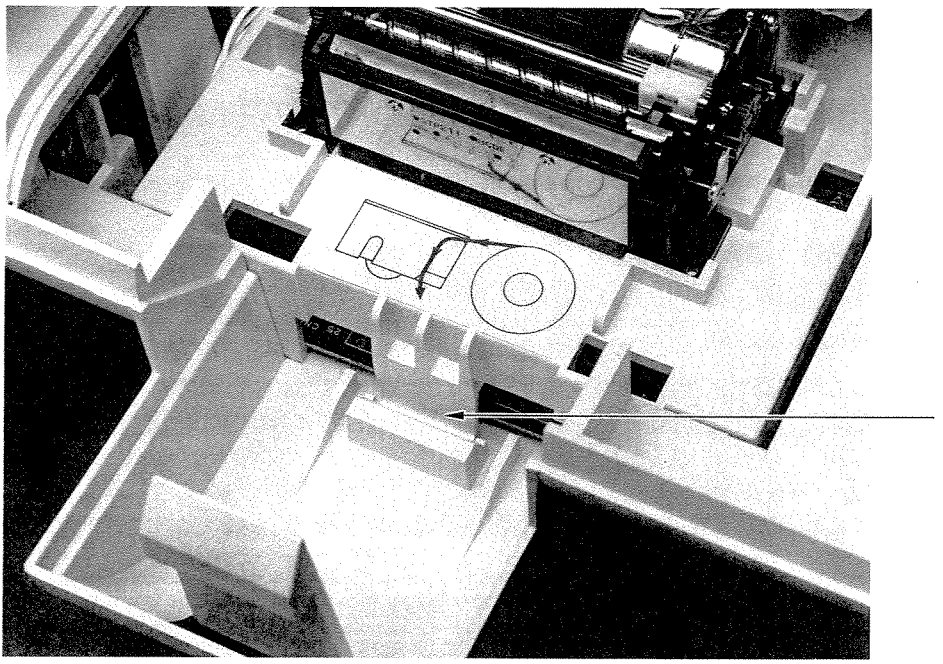


Figure 8-5
Printer Module Lever

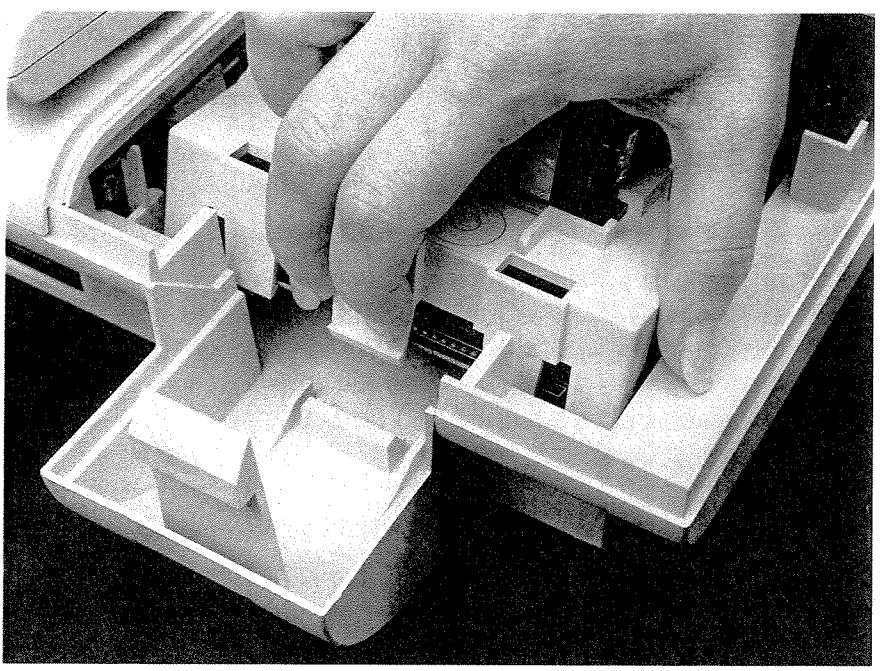


Figure 8-6
Removing the Printer Module

b. The module hooks under a ledge at the front and snaps into position at the back with a small lever (Figure 8-5). Press in on the lever at the back and lift up on the printer (Figure 8-6). Raise the module partially out of its cavity by lifting up and back.
c. The module will still be connected to the instrument by the power cable. The keyed connector on this cable has a small lever on each side; press these together and pull apart the two sides of the plug to disconnect the power cable (Figure 8-7). Completely remove the module from the instrument.

5. **To replace the printer module:**
   a. Obtain the replacement printer module, to which is attached an interface cable and jumper cable. Be sure both cables are firmly attached to their appropriate receptacles on the module by pushing *straight down* on the connectors (the jumper cable connects into the board immediately to the left of the printhead).
   b. Carefully set the new module onto the edge of the CLINITEK 100 instrument or partially into the instrument cavity. Plug the power cable into the jumper cable by pressing together the two sides of the connector. Notice that the two sides fit together in only one direction.

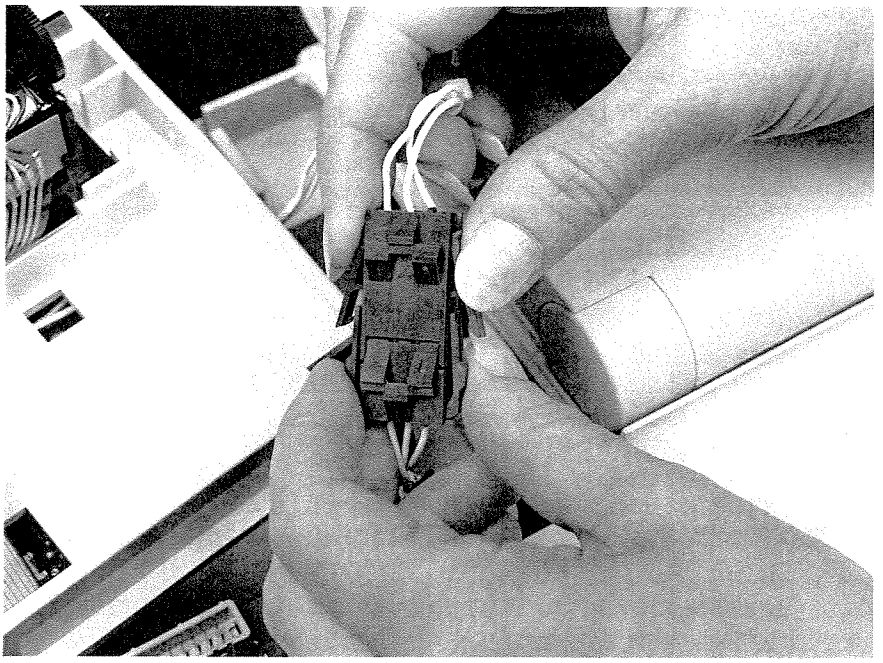


Figure 8-7
Disconnecting the Power Cable

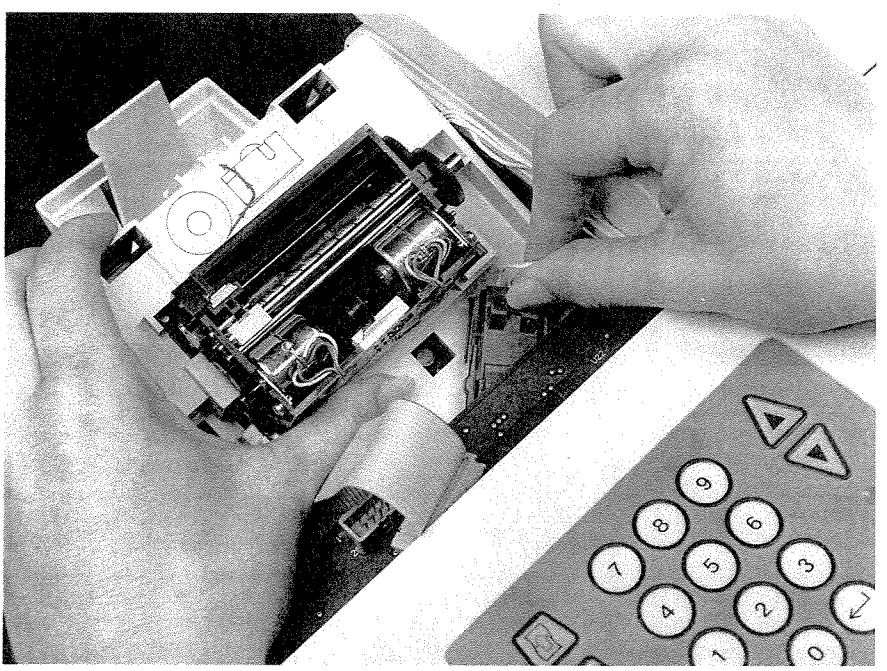


Figure 8-8
Reinstalling the Printer Module

c. Place the module into its proper position in the cavity of the instrument by lowering the front of the module down and forward under the ledge. At the same time, maneuver the connector so it slides under the ledge along with the module (Figure 8-8). Then lower the back of the module and press down firmly until it snaps into place.
d. Carefully plug the interface cable onto the rows of pins on the PC board. Press *straight down* on the pins until the cable is securely connected.
e. Replace the roll of paper, as instructed in Section 6, "Periodic Maintenance."
f. Plug in and turn *on* the CLINITEK 100 instrument. Test the new printer by printing out a record through the Data Recall prompt (in the Main Menu) or by performing several Reagent Strip tests. (If you had turned the internal printer *off* prior to replacement of the module, be sure to turn it back *on* through the Instrument Setup Routine.)
NOTE: If "Printer Error" is displayed when attempting to print, check for a tight and proper connection of each of the two cables.

SERVICE AND REPLACEMENT PARTS

Where To Call For Service

When problems arise during operation of the CLINITEK® 100 instrument, first refer to Section 7, TROUBLESHOOTING. Avoid erroneous instrument/Reagent Strip results by following proper instrument and Reagent Strip procedures. If the problem cannot be solved and an instrument defect is apparent, contact your nearest authorized Customer Service or Instrument Service Representative. In the United States, contact the Customer Service Department of Bayer Corporation, Diagnostics Division, by calling toll free 1-800-348-8100 for complete information regarding service for your CLINITEK 100 instrument. In countries other than the United States, contact the nearest Bayer Diagnostics office for service information.

If the problem centers on the Bayer Diagnostics Reagent Strips for Urinalysis, the CHEK-STIX® Control Strips for Urinalysis, or operator technique, contact the Customer Service Department (continental U.S. customers only). For Customer Service outside the United States, contact the nearest Bayer Diagnostics office.

Before calling for instrument service, collect the information requested in the following "Preservice Checklist." This information will help the Customer Service Representative to identify the probable cause of instrument malfunction.

CLINITEK® 100 Preservice Checklist

For reference, record the following information:

Instrument Serial Number_____

Installation Date_____

	YES	NO
1. Has Section 7, TROUBLESHOOTING, been reviewed?	☐	☐
2. Does the feed table move out to the "load" position when the instrument is first turned *on*?	☐	☐
3. If Step 2 is NO—		
• is the instrument plugged into a live AC electrical outlet?	☐	☐
• is the line fuse defective? (See Section 8.)	☐	☐
• is the Program Card firmly in place and properly oriented?	☐	☐
4. Does the display show the appropriate series of messages when the instrument is first turned *on*?	☐	☐
5. Do the three colored LEDs flash *on* and *off* when the instrument is performing its "Self-Test"? (See Section 1, "Optical System.")	☐	☐
6. Does the feed table move into the "storage" position shortly after ⏀ is pressed?	☐	☐
7. Is the keyboard operating properly?	☐	☐
• Is the instrument taking a reading on a Reagent Strip?	☐	☐
8. Does a Bayer Diagnostics Reagent Strip dipped into a negative control urine provide correct readings?	☐	☐
• Has a second strip been tried?	☐	☐
9. Does the Reagent Strip name displayed correspond to the Bayer Diagnostics Reagent Strip being used?	☐	☐
10. Is the display area functioning properly?	☐	☐
11. Does the display show the appropriate test names and numbers? (See Tables 1-1 to 1-8.)	☐	☐
12. Is the feed table insert properly positioned on the feed table?	☐	☐
13. Is the feed table insert or calibration chip scratched or damaged?	☐	☐
14. Does the feed table operate properly?	☐	☐

If not, describe:_____

_____

15. Please record the software version being used (displayed below the instrument name when power is first turned *on*)._____

Replacement Accessory Items

Product No.	Description
1364	CHEK-STIX® Combo Pak Control Strips for Urinalysis
1360	CHEK-STIX® Positive Control Strips for Urinalysis
1365	CHEK-STIX® Negative Control Strips for Urinalysis
5773	Thermal Printer Paper (5 Rolls)
5371	Epson LX-series Printer
5255	CLINITEK® Form Printer
5256	CLINITEK® Form Printer Ribbon Cartridge
5163	CLINITEK® Report Forms

In the United States, the above Accessory Items are available from your authorized CLINITEK 100 distributor. Outside of the United States, contact the nearest Bayer Diagnostics office.

Replacement Parts

Part No.*	Description
95001474	Feed Table Insert—4¼ inch (○)
95001476	Feed Table Insert—3¼ inch (△)
40151108	Instrument Line Fuse—1.0 Amp, Slo-Blo, 5x20mm (for 115 VAC instruments)
*	Instrument Line Fuse—1.0 Amp, Time Delay (for 100 VAC instruments)
*	Instrument Line Fuse—2.0 Amp, Time Delay (for 220 or 240 VAC instruments)
6040	Program Card
95001186	Printer Module
40330028	AC Power Cord
99957728	CLINITEK 100 Service Manual

In the United States, the above Replacement Parts are available directly from Instrument Service, Bayer Corporation, Diagnostics Division, P.O. Box 2004, Mishawaka, IN 46546.

*Outside of the United States, contact the nearest Bayer Diagnostics office.

COMPUTER AND PRINTER INTERFACE

General Information

This appendix is written primarily to assist a software engineer in writing a program for interfacing the CLINITEK® 100 Urine Chemistry Analyzer to a host computer via the serial port on the instrument. It also contains information for interfacing a printer via the parallel port on the instrument.

Computer Interface–Data Transfer To/From a Computer

EIA-232D (Serial) Port

The EIA-232D (serial) port is the means by which Reagent Strip data or test information is transferred to a computer or data management system. In addition, specimen number "load lists" are downloaded to the instrument from a host computer via this port. The EIA-232D standard was accepted in 1986 by the Electronics Industries Association (E.I.A.) as the revised and upgraded standard of the earlier RS-232C version.

The interface connector for the serial port is found on the rear of the instrument and is labeled "EIA-232-D." The connector has the following characteristics: DCE Male, DB25, EIA-232D. The data interface operates using 7-bit ASCII in a serial asynchronous data transfer method. Each character is preceded by one start bit, followed by eight data bits/no parity, and ends with one stop bit.

CAUTION: The serial port can be interfaced *only* to an EIA-232D or RS-232C connector; use of any other configuration of serial port (e.g., RS-422, RS-423, RS-485) may result in instrument errors or damage. If a different serial configuration is required (for example, because the interface cable must be longer than is suggested for an EIA-232 or RS-232 cable), a converter box must be used between the serial port on the instrument and the alternate cable. (Depending upon your computer requirements, you may also need a second converter box on the computer end of the cable.)

The operating characteristics of the port may be defined by the operator in the **Setup** Routine, which is accessed through the **Menu** Function (refer to Section 2, Part B). The following settings may be configured:

Settings	Description
1. Computer Port	Enables output from EIA-232D port in the handshake mode: On Off
2. Baud Rate	Selects the transmission speed: 300 600 1200 2400 4800 9600
3. Date Format	Selects the format for the date: YY-MM-DD MM-DD-YY DD-MM-YY
4. Time Format	Selects the format for the time: 24 Hour 12 Hour
5. Identify Abnormals	Sends flag with abnormal results (see "Possible Clinical Results"): No Yes
6. Identify First Abnormal Level	Selects the first level at which the abnormal flag will be sent (option available only with Identify Abnormal set to "Yes"—see "Possible Clinical Results").
7. Specimen ID Entry	Sends ID number with data: No Yes
8. Color/Clarity Entry	Sends Color and Clarity with data: No Yes
9. Plus System	Sends results in "Plus" system (1+, 2+, 3+) rather than semiquantitative or qualitative results: No Yes

Software Handshaking

The computer protocol can be written to operate in either of two modes for sending and/or receiving data to and from the CLINITEK 100 instrument:

1) **Handshake ON:** The computer handshake mode allows a connected computer to "request" that a set of data be transmitted or that the last set of data be resent. Recovery of bad data is possible through the use of special control characters (defined below). If the computer port is turned ON, the handshake mode is automatically enabled.
2) **Handshake OFF:** If the computer port is turned OFF, the instrument will still transmit data to a host computer under the following three conditions:
   a) the host computer must be connected to the CLINITEK 100 instrument through the serial port;
   b) the host computer must be turned *on;* and
   c) all data is transmitted in a non-handshake mode.

   The data is transmitted to the connected computer as soon as it is available (that is, each time a strip is run on the instrument); the results are NOT stored in the instrument memory, regardless of whether a computer is connected to receive the data. No response is required from the computer; however, once data is sent, it is gone and cannot be recovered. The data format is such that a printer with a serial port could be connected if desired.

Data transmission from the CLINITEK 100 can be suspended by the connected computer by either of two methods:

1) The hardware handshake lines may be used to stop data transmission.
2) An XON/XOFF software protocol can be used to stop data transmission temporarily. Sending the XOFF control character to the CLINITEK 100 stops data flow; sending the XON control character starts data flow again. When the instrument is turned *on,* the XON condition is in effect. Before any character in a data set is transmitted, the input buffer is checked; if an XOFF (DC3; 13Hex) has been received, no transmission will occur until an XON (DC1; 11Hex) character is received.

The instrument sends its data in frames beginning with an STX (Start of Text; 02Hex) and ending with an ETX (End of Text; 03Hex). Each frame contains one full set of patient data.

The special control characters and functions are listed in Table App I-1 below:

ASCII	Hex	Function/Command
Data Control:		
CAN	18	Reset RS-232C port to default conditions.
DC1	11	XON–Enable transmission.
DC3	13	XOFF–Disable transmission.
Data Output Control (computer "handshake" operation)		
DC2	12	Prompt character; send one set of data. If an ENQ (05Hex) was the last control character received, send the instrument ID message instead.
ACK	06	Move to the next set of data for future data prompts.
NAK	15	Do not change to the next data set. (This control code is not required to be sent, since it is the default condition. Sending a DC2 will send the same data set again.)
Instrument ID Message (active only when *not* in Run Mode)		
ENQ	05	Send the instrument ID message when the next DC2 is received. This message includes information on the time and date, instrument identity and software revision, language and units, and Reagent Strip name.

Table App I-1

Cabling and Pin Specifications

The cable normally used to interface with the CLINITEK 100 instrument is a Null modem cable. This cable crosses pins 2 & 3, 4 & 5, and 6 & 20; pins 1 and 7 are straight through. Refer to Table App I-2 below for definitions of the pin assignments and hardware handshaking.

Pin Assignments:

Pin Number	Signal Name	Function	Type	Signal Source
1	CHAS GND	Protective Ground	Ground	N/A
2	TXD	Transmission Data	Data	CLINITEK 100
3	RXD	Received Data	Data	Computer
4	RTS	Request To Send	Control	CLINITEK 100
5	CTS	Clear to Send	Control	Computer
7	SIG GND	Signal Ground	Ground	N/A

(All other pins are unused.)

Hardware Handshaking:

RXD	Receive Data	This input receives control characters for software handshaking and data for ID#'s.
TXD	Transmit Data	This output sends test data, control characters, and instrument information.
RTS	Request To Send	This output line, when high, indicates to the computer that it may send data.

The following signal lines are NOT implemented:

DSR	Data Set Ready	Pin 6
DCD	Data Carrier Detect	Pin 8
DTR	Data Terminal Ready	Pin 20
RNG	Ring Indicator	Pin 22

Table App I-2

Computer Checksum

Computer checksum is provided to allow the computer system to detect transmission errors. Parity provides for character-by-character error checking, but it is only good for detecting single bit errors and does not detect double bit errors and missing characters. A checksum will detect these types of errors in transmission.

The checksum is a two-digit ASCII hexadecimal code transmitted immediately before the ETX character at the end of a data set. The checksum is calculated by adding all characters between the STX and ETX characters (not including the two checksum bytes), ignoring any carry. The result is an 8 bit number (0 to 255) that is converted into two hexadecimal ASCII codes ("0" - "9", "A" - "F"). For example, the binary code "01011010" equals "5A," and the two bytes "5" and "A" would be sent as the checksum. The least significant byte (in this example, "A") is sent first, followed by the most significant byte (in this example, "5").

Data Output Formats

Table App I-3 below shows the data format for each record sent by the CLINITEK 100 instrument.

CHARACTERS/COLUMNS

01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	
STX	CR	LF																				
#	X	-	X	X	X	SP	SP	SP	SP	SP	X	X	-	X	X	-	X	X	CR	LF		(Seq# and date)
I	.	D	.	SP	X	X	X	X	X	X	X	X	X	X	CR	LF						(If ID#'s selected)
C	o	l	o	r	:	SP	SP	SP	X	X	X	X	X	X	X	X	X	X	CR	LF		(If Color selected)
C	l	a	r	i	t	y	:	SP	X	X	X	X	X	X	X	X	X	X	CR	LF		(If Clarity selected)
CR	LF																					
X	X	X	SP	SP	SP	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF			(Analyte mnemonic & result)
										.												
										.												
										.	(Up to 9 additional tests)											
LSB	MSB	ETX																				

STX—Start of Text (02Hex)
CR —Carriage Return (0DHex)
LSB—Least Significant Byte of Checksum
SP —Space Character (20Hex)
ETX —End of Text (03Hex)
LF —Line Feed (0AHex)
MSB—Most Significant Byte of Checksum

Table App I-3

All analyte/result lines are 20 characters long, including the Carriage Return and Line Feed. There are three spaces between the mnemonic and the result field for each analyte except SG and pH, for which there are four; the number of spaces following the result field varies. Table App I-5 shows all possible results for each of the ten analytes plus color and clarity.

Depending upon the Bayer Diagnostics Reagent Strip being used, there are at most 10 lines of analytes/results. The order in which the analytes are output is the same order in which they are read by the instrument, as shown in Table App I-5; this order is the same for every configuration of Bayer Diagnostics Reagent Strips that can be used on the instrument.

Table App I-4 shows the data format of the instrument ID information that is sent by the CLINITEK 100 instrument when an ENQ and a DC2 are sent to it by the computer.

CHARACTERS/COLUMN

01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	
STX	CR	LF																		
I	D	SP	0	9	:	5	1	0	5	-	2	2	-	9	2	CR	LF			(18 characters)
A	M	5	7	7	2	SP	SP	SP	F	3	.	0	2	CR	LF					(16 characters)
E	N	G	L	I	S	H	SP	C	O	N	V	.	CR	LF						(20 characters maximum)
M	U	L	T	I	S	T	I	X	SP	1	0	SP	S	G	CR	LF				(20 characters maximum)
LSB	MSB	ETX																		

Table App I-4

Line 1 identifies this as an ID message and gives the date and time programmed into the instrument. Line 2 identifies the instrument as a CLINITEK 100 and gives the software revision. Line 3 identifies the language and units, if applicable, that are selected. Line 4 identifies the Bayer Diagnostics Reagent Strip currently selected.

NOTE: The instrument will send an ID message only while in the **Standby** Mode; the message will not be sent while in the **Run** Mode.

After correctly receiving the instrument ID message, the host computer must respond by sending an ACK. Failure to do so will cause the instrument to continually send the instrument ID message for each DC2 prompt received.

Data Reception from a Host Computer (Downloading)
The CLINITEK 100 instrument can receive a "load list" of specimen identification numbers from a host computer. Each ID# must contain exactly 10 numeric digits. The load list (up to 50 specimen numbers) is stored in the load list buffer of the instrument and can be printed by the internal printer of the instrument. The host computer can transmit the specimen numbers whenever the instrument is in the **Standby** Mode and information is not being printed by the instrument's internal printer. Operation is as follows:

1. The computer sends an STX.
2. The instrument responds with an ACK.
3. The computer sends a specimen ID number as:

   01 02 03 04 05 06 07 08 09 10 11 12
   STX X X X X X X X X X X ETX (10 numeric digits)

4. If the CLINITEK 100 instrument can accept the number, it is stored in the load list buffer and an ACK control character is sent to the computer. The remaining specimen ID numbers can then be sent. For each additional number, the computer sends an STX as in Step 1 (the instrument does not respond with an ACK) and then sends the ID number (Step 3).
5. If the instrument cannot accept the number, a NAK control character is sent to the computer. A NAK will be sent if the instrument is not in the **Standby** Mode or if the load list buffer is full.
6. The computer must send an EOT at the end of the transmission of ID numbers. When the EOT (04Hex) is received by the instrument, and if there are ID numbers in the buffer, the number(s) will be printed by the instrument's internal printer as a "load list."

   NOTE: If "Specimen ID Entry" was selected as "No" in the **Setup** Routine, the load list buffer will clear after printing the load list. This allows for another load list to be sent. If "Specimen ID Entry" was selected as "Yes," the load list will be retained in the buffer until recalled through the **Run** Mode.

NOTES:

a) The ACK or NAK will be returned within 25 ms. of reception of the ETX.

b) At Baud rates of 1200 or greater, a minimum delay of 5 ms. must be placed between each character, regardless of whether or not handshake is used.

Possible Results

Color	Yellow	Dk Yellow	Straw	Amber	Red	Orange	Green	Other	
Clarity	Clear	Sl Cloudy	Cloudy	Turbid	Other				
GLU	Negative	Trace	250 mg/dL	500 mg/dL	>=1000 mg/dL				
BIL	Negative	Small	Moderate	Large					
KET	Negative	Trace	15 mg/dL	40 mg/dL	>=80 mg/dL				
SG	<=1.005	1.010	1.015	1.020	1.025	>=1.030			
pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	>=9.0
PRO	Negative	Trace	30 mg/dL	100 mg/dL	>=300 mg/dL				
URO	0.2 EU/dL	1.0 EU/dL	2.0 EU/dL	4.0 EU/dL	>=8.0 EU/dL				
NIT	Negative	Positive							
BLO	Negative	Trace	Small	Moderate	Large				
LEU	Negative	Trace	Small	Moderate	Large				

Table App I-5

NOTES:

1. If the "Plus System" option is being used, the results are modified as follows:
   GLU, KET, PRO, BLO, LEU: Results greater than Trace are 1+, 2+, and 3+
   BIL: Results greater than Negative are 1+, 2+, and 3+

2. If "Identify Abnormals" is selected as "Yes," any result greater than Negative may be flagged for GLU, BIL, KET, PRO, NIT, BLO, and LEU; any result greater than 1.0 EU/dL for URO may also be flagged. The lowest level that is considered to be abnormal is determined through the Setup Routine. Abnormal results are flagged with an asterisk (*), immediately after the mnemonic abbreviation for the analyte. If not flagged, a SPACE character follows the mnemonic. In both cases, the line length remains the same.

Printer Interface–Data Transfer to a Printer

Printer (Parallel) Port

The printer (parallel data) port is of the "Centronics" style of interface with a DB-25 connector. It is provided for use with either of two types of printers:

1. CLINITEK® Form Printer–a special format of data is generated for this form printer when "Form Printer" is selected as "ON" in the **Setup** Routine. The Form Printer (Product No. 5255) includes an interface cable to connect the printer to the CLINITEK 100 instrument.
2. Any standard 80-column printer having a Centronics style of interface–"80 Column Printer" must be selected as "ON" in the **Setup** Routine. The interface cable that is used to connect the 80-column printer to the CLINITEK 100 must contain a DB-25 female connector (standard IBM configuration).

Pin Specifications for Printer Interface (DB-25 Female Connector)

Pin Number	Signal Name	Function	Note	Signal Source
1	STROBE-L	Data Strobe	1	CLINITEK 100
2	Data 1	Parallel Data Line		CLINITEK 100
3	Data 2	Parallel Data Line		CLINITEK 100
4	Data 3	Parallel Data Line		CLINITEK 100
5	Data 4	Parallel Data Line		CLINITEK 100
6	Data 5	Parallel Data Line		CLINITEK 100
7	Data 6	Parallel Data Line		CLINITEK 100
8	Data 7	Parallel Data Line		CLINITEK 100
9	Data 8	Parallel Data Line		CLINITEK 100
11	BUSY	BUSY Line		Printer
12	DS	Document Status or Paper Out		Printer
18	SIG GND	Signal Ground	2	N/A

NOTES:

1. STROBE-L (Data Strobe): "-L" indicates active low signal.
2. SIG GND (Signal Ground): Pins 19 through 25 are also connected to the signal ground.

Table App I-6

CLINITEK® 100
Urine Chemistry Analyzer

Instrument Serial No. _____ Installation Date _____

MANUFACTURER'S WARRANTY

(U.S. Customers Only)

Bayer Corporation, Diagnostics Division ("Bayer") warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one (1) year from the later of the date of original purchase or installation (except as noted below). During the stated one-year period, Bayer shall replace with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. A 90 day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and Bayer shall not be required to make any repairs or replace any parts which are necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer instruments caused by the use of reagents other than reagents manufactured or recommended by Bayer.
3. Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY BAYER.

Limitations of Liability

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service, purchaser must contact the Customer Service Department of Bayer Corporation, Diagnostics Division, by calling toll free 1-800-348-8100, for assistance and/or instructions for obtaining repair of this instrument.